EXHIBIT 5

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION,	:	MDL NO. 2875
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

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Veritext Virtual Zoom Videotaped deposition of RENA M. CONTI, Ph.D., taken on Thursday, February 10, 2022, in Glenside, Pennsylvania, commencing at 10:17 a.m. Eastern Standard Time, before Jamie I. Moskowitz, a Certified Court Reporter and Certified Livenote Reporter.

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EXHIBITS

REQUEST PAGE

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RENA M. CONTI, Ph.D.

THE VIDEOGRAPHER: We are going on the record at 10:17 on February 10th, 2022. This is Media Unit Number 1 of the video recorded deposition of Rena Conti regarding the valsartan litigation.

My name's Justin Bilely from the firm Veritext, and I'm the videographer. The court reporter is Jamie Moskowitz from the firm Veritext.

All counsel will be noted on the stenographic record. Will the court reporter please swear in the witness, and then we can begin.

* * *

P R O C E E D I N G S

THE COURT REPORTER: The attorneys participating in this deposition acknowledge that I am not physically present in the deposition room and that I will be reporting this deposition remotely.

They further acknowledge that, in lieu of an oath administered in person, the witness will verbally declare his testimony in this matter is under penalty of perjury.

The parties and their counsel consent

to this arrangement and waive any objections to this manner of reporting. If there are any objections, please state them at this time.

* * *

THE COURT REPORTER: Hearing no objections, I will swear in the witness.

* * *

RENA CONTI, after having been first duly sworn, was examined and testified as follows:

* * *

THE COURT REPORTER: Okay, Counsel, please proceed.

MR. GOLDBERG: Thank you.

EXAMINATION BY MR. GOLDBERG:

Q Good morning, Dr. Conti. My name is Seth Goldberg. I'm with the law firm Duane Morris, and we represent the ZHP parties in this action. I'm going to be asking you questions during the deposition today on behalf of all of the defendants in the case, as well.

Can you state your name for the record, and your current address?

A Sure, Rena Conti, 2 Overlea Way, Glenside, PA 19038.

Q Okay. You've been deposed before, Dr. Conti?

A I have.

Q You understand, throughout the day, I'm going to ask you questions. You're going to provide answers. And if -- during the day, if we can try not to talk over one another, that would be helpful.

Your counsel or plaintiff's counsel may assert objections from time to time. Unless they instruct you not to answer, you're to answer the question, okay, not withstanding the objection. If you don't understand --

A I understand.

Q If you don't understand a question I've asked, please ask me to clarify it or rephrase it. If you answer it, we'll assume that you understood it. Okay?

A I understand. Thank you.

Q If you need to take a break at any time, no problem. Just ask.

A Okay.

Q Have you taken any medications this morning that may impair your testimony today?

A I took a couple of Tylenol, but I

don't think that's going to --
Q Hopefully -- okay.
Why don't we talk a little bit about your professional background?
Can you explain what your current position is at Boston University?
A Sure.
I am associate professor in the Department of Markets, Public Policy and Law at the business school at Boston University. It's called Questrom School of Business. In addition, I am co-director of the institute -- of an institute called Technology & Policy research Institute, which is an institute across the business school and the law school that focuses on issues related to technological innovation, its -- and its regulation.
Q Are you -- are you currently teaching any courses?
A Sadly, yes, I am. I am --
Q What courses?
A I am teaching Strategy in the Biopharmaceutical Industry --
COURT REPORTER: I'm sorry. You're teaching...
THE WITNESS: I teach Strategy in the

Biopharmaceutical Industry. That is the class that I have taught for the better part of 20 years.
BY MR. GOLDBERG:
Q What is that course about? Just give me a -- give me a thumbnail sketch of that course.
A Sure.
It's about the financing, organization and regulation of the pharmaceutical industry, and how firms in this industry, most notably the -- the pharmaceutical manufacturers themselves, innovate price, get reimbursed and generate revenue.
Q Did you write a textbook for that course?
A I'm in the process of writing a textbook now. Like I said, I have taught this class for the better part of 20 years, at Harvard University, at the University of Chicago and now at Boston University. And I developed many materials, including case studies, that are now the industry standard.
I have a number of textbooks --
Q Hang on --
A Wait. Wait. So I was the economist on the National Academy of Science's recent report

on drug pricing and regulation, and it's that report that the committee developed that is actually the -- one of the textbooks that we use in my class.
Q You said something about industry standard. I was trying to ask, industry standard for what? What -- you said something was the industry standard.
A Oh, the materials that -- that I've developed for my course and developed in -- in other contexts during my research, are very widely used to teach about the industry, about the pharmaceutical industry.
Q In terms of your expert consulting, you have an associate position at Greylock McKinnon?
COURT REPORTER: Where?
MR. GOLDBERG: Greylock McKinnon; is that correct?
THE WITNESS: I'm sorry, is that a question?
BY MR. GOLDBERG:
Q Yes.
A Okay. Right. So I have worked with Greylock McKinnon and Associates on -- on health litigation matters, again, largely in the pharmaceutical industry -- products, I guess, in the

pharmaceutical industry, again, for the better part of 20 years.
Q And what do you do at Greylock McKinnon?
A I provide expert services for -- in support of litigation.
Q Do you do any consulting with Greylock McKinnon that is not litigation related?
A No.
Q Are there particular kinds of litigation that you work on for Greylock McKinnon?
A Again, all of it's in -- on the pharmaceutical industry, related to pricing, reimbursement, coverage, competition and regulation. And I have been involved in a variety of antitrust matters, and a variety of -- of other types of legal matters.
Q On a -- on a, you know, given day or given week, how many matters are you handling in your capacity as an -- this academic affiliate at Greylock?
A It really depends on the time period and the year. Right now, I think I have maybe three cases that I'm working on in various forms.
Q Well, are you working as an -- as an

expert in all three of those cases?
A Yes.
Q Okay. And are those three cases products liability cases? Are they antitrust cases? What's the subject matter of those cases?
A One of them is a liability case, and -- well, actually -- yeah. One of them is a liability case, and two others are antitrust cases.
Q Generally, can you -- can you describe the mix on a percentage basis, between antitrust, patent, products liability, that you -- that you generally have?
A So do you mean in relation to the work that I do at -- with Greylock McKinnon --
Q Yes.
A -- or other -- okay.
Q Well, are you doing expert work outside of Greylock McKinnon?
A Yes, I am.
Q Okay. Is that -- I guess we'll -- we'll get to your CV, and maybe you can show me on your CV where that is.
But why don't we take it first with Greylock McKinnon, where your -- what the case mix is from antitrust, patents and other subject

matters?
A I don't quite understand what you mean by "patent."
Q Patent, patent, patent or intellectual property. Are you doing any expert work in intellectual property matters?
A Not -- so patents are obviously an important part of the industry. But -- and they are related to the work that I'm doing, but I'm not doing any patent litigation work, if that is what you're asking.
Q Yeah. So I'm asking, what is the -- you know, the -- the makeup of the different subject matters that you're working on as an expert, as a general matter. You said antitrust. You said products liability. Are there other types of matters that you work on?
A Okay. So at Greylock McKinnon, I'm largely working half and half on product liability and antitrust. I would say I have increasingly worked on product liability over the past couple of years, and -- but generally, there's a mix of that now.
Q And explain what your expert work is when you're doing it not through Greylock McKinnon.

Are you -- do you have an independent expert consulting firm that you're just doing independently?
A I am working on a number of matters that Greylock McKinnon has conflicts with, and I'm -- they are largely either business disputes between pharmaceutical firms --
COURT REPORTER: Between what?
THE WITNESS: Between pharmaceutical firms.
COURT REPORTER: Uh-huh.
THE WITNESS: Or matters related to government work that -- where I am serving as an expert and there are government agencies involved.
BY MR. GOLDBERG:
Q Can you describe what that -- can you give us a little bit more detail about what those kinds of matters are?
MR. HONIK: Dr. Conti -- Dr. Conti, let me instruct you that while Mr. Goldberg's questions are fine, not to reveal any matters, particularly in the litigation sphere, in which there may not have been a normal date to disclose your involvement. And so be very

circumspect about that. Thank you.
THE WITNESS: Thank you.
On the government investigations and -- I am serving as an expert and have served as an expert in the past. And I can't provide any details.
BY MR. GOLDBERG:
Q Are there matters that you worked in terms of government investigations in the past that you can provide details about what the -- what the subject matter is of the investigation? Are you investigating cGMP practices? Are you investigating fraud? Are you investigating, you know, something related to the business? I'm just trying to get a sense of what you do as an expert in government investigation.
A Sure. So every single day, all day long, all I do is think about the financing, the organization and the regulation of the pharmaceutical industry. So you can kind of fairly surmise from that that the work that I'm doing, either in business disputes between industry members is related to financing, organization and regulation of these products, and in the government work that I do, again, it's all related to financing,

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organization and regulation.
I have been a special consultant to the Office of Generic Drugs for years, and have been involved in the regulation of pharmaceuticals by the Food and Drug Administration for a long time.
And so a lot of the -- a lot of the work that I work on for government agencies is related to the regulation of these products.
Q Is there a particular aspect of the regulation of these products that you focus on? And when you're -- let me qualify that. Regulation of pharmaceutical products that you focus on?
A So I would say I have two broad expertise. The first is on pricing of these products; how it is priced by the pharmaceutical industry themselves, what are the factors that lead to prices being high, changing over time, increasing or decreasing with competition, both in the branded and specialty -- or branded and generic market.
And then the second broad category of expertise is on competition, and specifically what are the factors that drive pharmaceutical companies to enter specific types of markets, particularly generic markets; what are the conditions upon which they can enter those markets; how does competition

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evolve over time; and to what extent do regulatory agencies support entry and sustained competition over time.
Q I just want to come back -- I'd just like to clarify one thing.
Going back to when you were talking about your coursework, and you -- the -- the materials that you said, you know, are used and have become an industry standard, when you -- when you're talking about the industry standard, you're saying the industry standard for teaching this stuff at universities. Is that -- is that what you mean?
A Well, right. So many of my articles that I've published on the pricing of these products and the regulation of these products are used by myself to teach, but are also used by many other experts in the field to teach about this industry. And that's actually one of the conditions of tenure, is that there is an industry standard that -- that is met.
And then I have developed coursework for materials that are used for teaching, case studies, that type of stuff, that are used by myself, and they are used by Harvard University professors. And they are used by Wharton professors

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and others.
Q Okay. Got it.
Back to the expert stuff, in terms of working as an expert on behalf of plaintiffs, on behalf of defendants, do you -- do you do more of one or the other?
A So I have worked on the defendant side, largely in business disputes between different firms. In those cases, matters largely related to production of products and the regulation of those products have been domain.
And then I would say -- I mean, obviously, in the government work I've done, it's largely been on the side of the government and taxpayers, consumers, that are insured by the government.
And then -- and then I have done plaintiff's work on -- largely on antitrust matters.
Q And in products work, are you on plaintiff's side more than defendant's side?
A I'm sorry. I didn't hear the first part.
Q In products -- in products liability matters, or consumer class action matters, are you on plaintiff's side more than defendant's side?

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A I've largely worked on the plaintiff's side on those matters.
Q Have you represented any defendants in -- as an -- as an expert, in a products liability action or consumer class action?
A What do you mean by "consumer class action?" I'm sorry.
Q Like -- like the claims that we're here for today, the economic loss claim. Consumers are claiming they should get a refund for a product.
A Right. So I'm only -- I think I have three cases right now, one settled, on products liability. Each one of those cases, I was working on the plaintiff's side.
Q So in your -- your expert consulting experience, you've done three products liability cases; is that correct?
A Right, that I can talk about. Right.
Q And of those three, all three were on behalf of plaintiffs?
A Correct.
Q How many other products liability matters have you worked on that you can't talk about?
A At least one that comes to mind.

Q And in that one, can you tell us whether it's on behalf of plaintiffs or defendants?
A It was for the government.
Q Okay. In 2021, since we just finished the year, how much of your income was generated from your work as an expert witness versus your income as a professor?
A Somewhere maybe around a quarter.
Q Can you quantify that in dollars, what that expert work looks like on an annual basis?
A Do you mean in 2021?
Q Yes, sure.
A Okay. So pandemic year, I think I made approximately $100,000, maybe $80,000, somewhere around there, in 2021. Much of that was for cases that I worked on in previous years, not in -- in 2021.
Q Has the pandemic caused you to have fewer cases or work?
A Sadly, it's the reverse. All I do is sit in my house and work. I know you all probably feel the same way.
Q We all share that -- we all share that experience that we're working way more due to the pandemic, especially in litigation.

A I'm hoping to not be like that in 2022.
Q Yeah. In terms of the -- the business disputes where you've been an expert, have you represented pharmaceutical companies in those business disputes?
A Yes. Again, every single day, all I do is think about this industry. So in those matters, they've been pharmaceutical companies.
Q Are there -- are they generic companies or branded companies?
A Both.
Q Were any of the companies that you've represented in these matters, defendants in this case?
A No.
Q Have you -- let's talk about your retention in this matter. How did you -- how did you come about being retained in this matter?
A I was contacted by one of the principals at Greylock McKinnon and Associates, and asked if I would be interested in discussing with the attorneys the general outlines of the -- of the matter.
Q When was that first contact at

Greylock and your first meetings with plaintiffs' counsel?
A I think it was the month, or maybe the month previous, to when the pandemic started.
Q February of '20?
A February or March. I remember it was a very gray, cold day in Boston.
Q Do you recall who the lawyers were for the plaintiffs that you met with for the first time when you met -- had that first meeting in this matter?
A I think Ruben Honik and Conlee Whiteley and Layne Hilton were on that first call.
Q Have you --
A Maybe misremembering --
THE COURT REPORTER: I'm sorry, Ms. who?
THE WITNESS: Misremembering.
THE COURT REPORTER: Misremembering?
THE WITNESS: Misremembering. Sorry. My English.
MR. HONIK: It's a thing, not a person.
THE WITNESS: Exactly.

BY MR. GOLDBERG:
Q Well, whoever those plaintiffs' counsel were, had you known any of them before that first meeting?
A No.
Q Had you worked with any of the plaintiffs' counsel that are on -- on the plaintiffs' executive committee in this case prior to starting work on this matter?
A Not -- not that I can recall.
Q Do you know if Greylock McKinnon had a prior relationship with any of the lawyers that represent the plaintiffs in this matter?
A I don't know.
Q Do you have any matters currently pending with any of the lawyers that represent plaintiffs in this matter, any other matters that you're working on?
A I am sorry. What do you mean by "currently pending"?
Q Are you an expert in any cases that are currently pending where the lawyers who are plaintiffs in this case are representing parties in that case?
A I'm sorry. I don't -- I don't know

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what you mean by "currently pending".
Q Okay. Are -- are you doing expert work in any other case where the lawyers who represent the plaintiffs in this case are involved?
A Yes.
Q What case is that?
MR. HONIK: Let me caution you, Dr. Conti, that to the extent that there's no disclosure requirement in those matters, you should not reveal that today.
THE WITNESS: Thank you. I cannot provide any details.
BY MR. GOLDBERG:
Q Which lawyers in plaintiffs' committee are involved in that case?
MR. HONIK: Let me instruct you not to answer that for the same reason posited previously. It's effectively the same question and would reveal something -- excuse me -- and would reveal or disclose something that doesn't require to be disclosed at present. Thank you.
THE WITNESS: I'm sorry. I cannot provide an answer.
MR. GOLDBERG: Counsel, you can mark this portion of the transcript "highly

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confidential" so that it doesn't have to be disclosed outside of this matter, but I think we're entitled to know if Dr. Conti is working for the lawyers who represent the plaintiffs in this case in another matter.
MR. HONIK: She's already answered affirmatively to that question. But your pending question, to which I objected and instructed her not to answer, is -- is nearly a backdoor way of disclosing formally her involvement as an expert in cases in which there's not presently a disclosure requirement.
Accordingly, I've instructed her, and she's followed it, not to identify the lawyers because that identification effectively reveals the matter in which she's working. That's the basis. So please ask another question.
BY MR. GOLDBERG:
Q That matter, is that a products liability matter?
MR. HONIK: I instruct you not to answer.
BY MR. GOLDBERG:
Q Is it a -- is it an antitrust matter?
MR. HONIK: I instruct you not to

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answer and reveal the type of matter, litigated matter.
BY MR. GOLDBERG:
Q In that matter, have you been asked to render an opinion that's similar to the opinion you've been -- provided in this case?
MR. HONIK: Object to the form.
THE WITNESS: Are you asking whether that matter is on the pharmaceutical industry and its regulation and financing?
BY MR. GOLDBERG:
Q Sure. Let's start with that.
A Yes. Everything --
MR. HONIK: Excuse me.
THE WITNESS: Go ahead.
MR. HONIK: Without waiving the objection, I'll permit you to answer that and only that question.
THE WITNESS: Thank you.
Everything I work on in my teaching, in my research and in the expert work that I provide to the government and to other entities, is related to the financing, organization and regulation of the pharmaceutical industry.

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THE COURT REPORTER: Of the pharmacy -- of the pharmacy...
THE WITNESS: Of the pharmaceutical industry.
THE COURT REPORTER: Thank you.
THE WITNESS: Thank you.
BY MR. GOLDBERG:
Q When did you begin to work on that matter?
A I'm sorry, on -- on the industry?
Q No, on the matter that we've been discussing that you're working for plaintiffs' counsel in.
MR. HONIK: I'll instruct you not to answer that question for the same reason.
Seth, respectfully, these are just backdoor ways to try to get at your essential question, which is, tell me the other cases that you're involved in. And I won't allow Dr. Conti to reveal that.
MR. GOLDBERG: Well, I -- I disagree. I don't need to know the name of the case. I don't need to know the names of the other parties, but I do think we're entitled to know what Dr. Conti is doing for plaintiffs' counsel

in this case in other matters.
MR. HONIK: Yeah, I don't agree. And moreover, I don't understand the last part of your observation. I have permitted you to ask her many questions about all of the matters that she's involved with, for whom she's doing these in terms of segments of industry and otherwise.
But you know and I know that if you're involved as an expert consultant in a case in which the date for disclosure of experts has not yet arrived, that that is information that can't be revealed. So please move on.
BY MR. GOLDBERG:
Q How much money have you made from plaintiffs' counsel in that case?
MR. HONIK: Without waiving the objection, you can answer. I think you did, didn't you?
THE WITNESS: Thank you. None.
BY MR. GOLDBERG:
Q Do you have your retention in that case through Greylock McKinnon?
A Yes.
Q Are you charging in that matter the

same fee, hourly fee, that you're charging in this matter?
A I don't know.
Q Have you generated an invoice yet in that matter?
A No.
Q Okay. Going back to the beginning of your retention in this case, prior to being retained or at least meeting plaintiffs' counsel in February, March 2020, had you done any research into valsartan?
A Yes.
Q In -- in what capacity did you do research into valsartan prior to that February, March 2020 time period?
A In two separate capacities. The first is that I have a longstanding interest in some types products --
COURT REPORTER: In some what?
THE WITNESS: In some types of pharmaceutical products, which include drugs that are used to treat heart disease, valsartan being one of them, but there are many others.
And then, in the other capacity, I have spent a fair amount of time thinking about

generic entry in product markets, and have thought a lot about -- I have thought about and also researched the entry of manufacturers in this particular market.
BY MR. GOLDBERG:
Q When you say," in this particular market," what were you -- define what you mean by "in this particular market."
A In the valsartan market.
Q When you were studying or researching valsartan in connection with your interest in heart disease, what was the nature of the research?
A Pricing, promotion and --
THE COURT REPORTER: And -- and what?
THE WITNESS: And access to these products.
BY MR. GOLDBERG:
Q What do you mean by "access"?
A Patient use.
Q Were you looking at it from an efficacy standpoint?
A Safety and efficacy are both part - are both determinants of access. So I guess, generally, yes.
Q But at that -- at that time, you

became generally familiar with the safety and efficacy of valsartan at that time?
A I think I would think -- I think about that differently as an economist. So I am interested, again, in the pricing and the reimbursement and in the utilization of these drugs. Safety and efficacy of products are one of the determinants -- or two of the determinants of people using these products.
Q Okay. So you -- you were kind of thinking about how many people are using it, the number of people who are using it, and that's sort of indicative of its safety and efficacy in some way?
A No.
Q Okay. Do you want to explain?
A Sure.
So I was thinking about the pricing of this product market, which included the -- the valsartan products, but not only the valsartan products. I've been thinking about the reimbursement of those products, so who pays what for them. And then I have -- I researched the use of those products, so what determines the use of those products, what are the general patterns of use

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in national prescriptions, in dispensing of prescriptions in certain -- by certain --

COURT REPORTER: I'm sorry. In certain?

THE WITNESS: Sorry. In certain markets, et cetera.

BY MR. GOLDBERG:

Q And by "these products," you're -- you said it's more than valsartan. Are you talking hypertension products generally, or -- or is it heart disease products generally?

A Correct, drugs that are used to treat heart disease.

Q What was the timeframe of doing this kind of research?

A So I would say it overlapped with my -- the completion of my dissertation. So I finished my dissertation in 2007. I was researching the use of these products and their pricing before I finished my dissertation, so probably 2003, 2005. And then it continued on from there.

Similarly, I was very -- I've been very interested in competition, so when these products are expected to experience generic entry, undergo patent expiration; what types of product --

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or what types of firms enter into these markets; how much competition is there; to what extent do these prices go down over time; who uses these types of products. I think I've been thinking about that since at least 2010, 2011.

Q How about nitrosamines? Are you familiar with nitrosamines?

A Yes.

Q Prior to the February, March 2020 timeframe, had you done any work in connection with nitrosamines?

A Yes. There was -- President Bush had a council on cancer that released a report in 2010 about toxins, and specifically chemicals that can cause DNA damage and other types of human health harms that people might be exposed to in the United States. I read that report when it came out. I have been generally interested in -- in determining -- in chemicals that might impact consumer health.

As an expert in pharmaceutical economics and policy, this is kind of part of my -- my job, is to understand what these things are.

Q Have you done any -- authored any articles relating to nitrosamines?

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A No. This is just part of, again, the work -- this is all part of understanding a little bit more -- understanding this market. I was a chemistry major when I entered college, so I actually know what they are. So I -- I am familiar with what they are before I was an economist.

Q And in between 2010 and 2020, did you do any particular research on the occurrence of NDMA or NDEA in pharmaceutical products?

A Okay. I'm sorry. Can you restate the question or just -- just ask the question again?

Q Sure.

Between 2010, when you said that article -- that article came out, and February 2020, did you do any research in -- in the area of the occurrence of NDMA or NDEA in pharmaceutical products?

A Right. So there's a various body of literature that was developing since, I think, at least the early 2000s on -- and actually, probably, before then, on -- on chemical contaminates that are harmful to human health. I did some coursework on that in -- at Harvard when I was finishing my -- when I was doing my Ph.D. And I have been interested in the topic especially since -- since I

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did my dissertation.

Q All right. I think you said you finished your dissertation before 2010?

A Right. I finished -- my dissertation was awarded in -- or my Ph.D. was awarded in 2007.

Q All right. My -- my question was -- I'm trying to be little more specific.

A Uh-huh.

Q My question was, since 2010, between 2010 and February of 2020, have you done any focused research on the occurrence of NDMA and NDEA, in particular, in pharmaceutical drugs?

A So I don't know what you mean by "focused research."

Q Well, has -- has the particular focus of research that you've done been the occurrence of NDMA or for NDEA in pharmaceutical drugs?

A So -- so again, the occurrence of these products and their threat to human health as part of the pharmaceutical industry is something that I have been aware of for a long time. And because of product contamination and adulteration in other product categories, not in valsartan, but in other drugs since at least 2007, 2008, that involve products made by Ranbaxy, products made at the Cidra

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plant, products made by Mylan, I am aware that there are a variety of chemicals that can contaminate pharmaceuticals and are harmful to human health. And NDMA is one of those products. It's not the only one.

Q And I'm asking about NDMA. Have you studied NDMA prior to February of 2020?

A NDMA and other products that have come up in my work between 2010 and 2020. Just like -- so, again, I -- if you are an expert in this industry, you know that there have been some very significant quality manufacturing lapses in pharmaceutical products. That includes contaminated Heparin. It includes the products that were made at Ranbaxy and ultimately at Mylan as well, and the products that were made at the Cidra plant --

COURT REPORTER: At the what?

THE WITNESS: By Glaxo -- by GlaxoSmithKline.

COURT REPORTER: I'm sorry. That were made at the...

THE WITNESS: Cidra plant at -- owned by GlaxoSmithKline in Puerto Rico.

There have also been other lapses in quality and in manufacturing that have occurred

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particularly around 2010, 2011, 2012. And I have been very interested in what exactly those quality lapses were and -- and what are the nature of the -- what are the harms to human health of those types of lapses.

So I am aware of nitrosamines, in addition to many other chemicals, being harmful to human health and have been aware of that during this time period.

MR. GOLDBERG: Can we pull up Tab 66?

BY MR. GOLDBERG:

Q Dr. Conti, I want to show you your retention agreement in this case. I don't think you need to take the time to go through the binder, but if you want to, I just want to pull this up and mark this as Conti 1.

(Whereupon, Exhibit Conti 1 was marked for Identification.)

BY MR. GOLDBERG:

Q This is -- can you see that okay? You have it up on the screen?

A Yeah. I'm going to go get my binder.

Q It's going to be Tab 66 in that binder.

A Okay. Great.

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Q Do you have Tab 66, what we have marked as Conti 1, in front of you?

A I do. If you can just give me a second to read it, please.

Q Okay. This is your retention agreement with plaintiffs' counsel in this case?

A This is GMA's retention agreement with the attorneys on my behalf.

THE COURT REPORTER: I'm sorry?

THE WITNESS: On my behalf.

BY MR. GOLDBERG:

Q And it says that, in the first paragraph, that plaintiffs' executive committee has retained Greylock McKinnon Associates to provide consulting on economic issues and other related services.

What -- what are the related services that -- that you're providing?

A I don't know.

Q It goes on to say that you're going to -- you've been retained to provide expert testimony as it relates to issues of the calculation of damages.

A I see that.

Q Are -- are you -- do you understand

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that that -- that to be the scope of your testimony, the calculation of damages?

MR. HONIK: Object to the form and to the extent that it calls for a legal expert opinion.

You may answer.

THE WITNESS: I have produced a report that is calculating damages in this matter.

BY MR. GOLDBERG:

Q So the answer is, yes, you understand the scope of your work to be in relation to the calculation of damages?

MR. HONIK: Same objection.

You may answer.

THE WITNESS: Thank you.

So up until this period in time, what I have largely worked on in this matter is related to the calculation of damages.

MR. GOLDBERG: You can take that down, put that aside.

BY MR. GOLDBERG:

Q You generated a report in this matter in November of 2021. Can you describe, generally, what the process was for putting together that report?

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A I reviewed data. We --
THE COURT REPORTER: I'm sorry, Doctor. Can you repeat that?
THE WITNESS: Sure.
I discussed with the attorneys the availability of data to calculate damages in this matter, and also theories of liability that would determine how we calculated damages -- or how I calculated damages. I worked with my staff to -- and with -- and with the attorneys, to cull materials that would be helpful in the calculation of damages. And I also reviewed regulatory documents and other facts that are relevant to the calculation of damages.
And there's -- hold on. And there was lots of drafting, analysis, redrafting and finally, the final report.
BY MR. GOLDBERG:
Q How long do you think it took to generate the report from when you started to work -- work on it?
MR. HONIK: Seth, can we agree that when you use the word, "report," you're referring to the expert declaration of

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Dr. Conti --
MR. GOLDBERG: Yes.
MR. HONIK: -- of November 10th of last year.
MR. GOLDBERG: Yes, the expert declaration.
MR. HONIK: Thank you.
THE WITNESS: I'm sorry. Can you ask me the question --
MR. HONIK: How long did it take you? That's what he asked.
THE WITNESS: To generate the report, correct?
BY MR. GOLDBERG:
Q Yes.
A Okay. Many months.
Q How many months?
A A lot. A lot of time because we were waiting -- we were discussing. We were waiting for data. We were -- and then calculating damages and then writing the report.
Q Many, a lot, do you have -- was it 10 months, more than 10 months?
A I would say -- I mean, we -- I was working on this, and staff was working on this

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pretty intently, at least starting over the summer.
Q Over which summer?
A Last summer, 2021.
Q You mentioned the staff. How big was your staff for this matter, and who were they?
A The people that I have worked most closely with are Bennett Erickson and Sarah Stone, both employees at Greylock McKinnon, both people that I work with pretty closely, generally. There might be some other staff that I don't know as well that have worked on this case.
Q Do you have a sense of how much time Bennett put into this matter?
A No. Bennett's worked a lot on this matter. But I -- I don't know. I don't see his billings.
Q Do you see anybody's billings for this matter, or does that all go to Greylock admins?
A I am very grateful for the work that Greylock does, and no, I don't see any of the billings. I don't -- I'm not involved in any of the administration.
Q Do you have a sense of how many hours you put into the declaration?
A Frankly, no.

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Q Do you expect it to be more than 25 hours?
A Yes.
Q More than 50 hours?
A Yes.
Q More than 100 hours?
A I would say close to 100 hours, sounds about right, but I don't --
THE COURT REPORTER: I'm sorry. One more time.
THE WITNESS: I don't have an exact accounting.
BY MR. GOLDBERG:
Q Your -- the retention agreement, which we marked as Conti 1, says your hourly rate is $675. Does that sound right to you?
A Hold on. Let me just look again.
Q Sure.
A So, yeah, it does. I think my hourly rate has gone up a little bit over time, maybe by $100, but I'm not exactly sure.
Q And for -- you would invoice your time to Greylock, as well?
A Yes.
Q What are -- what do Bennett -- what

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are Bennett and Sara's backgrounds? Are they Ph.D.s? Are they -- what -- what do they do?
A So Bennett and Sarah both have -- are both highly trained quantitative people. I would say Sarah largely assists me on research through identifying documents and specific facts that might be helpful. I would say Bennett largely works on data cleaning, manipulation and analysis. I have not seen either of their CVs, but I have worked very closely with them for a long time.
Q When you think about your expert declaration, it's broken up into -- sort of at the beginning -- your calculations of damages kind of appear at the end of the declaration. Did -- did either Bennett or Sarah do more in terms of the calculations of damages? How did the work break up in terms of writing, drafting your report?
A Okay. I think you're mischaracterizing my report, number one.
So the estimate of damages is found in the front, and then the discussion of how to calculations -- how to calculate the report is kind of in the middle. And then the actual -- actual calculations are summarized at the end. And then there are appendices that provide the details of the

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data and the specific calculations.
I wrote my report.
Q What do you mean by that?
A I mean I wrote my report.
Q Okay. You mentioned that there were lots of drafts and back and forth. You wrote it, you shared it with your colleagues at Greylock McKinnon to comment on it?
A I think that's a mischaracterization.
Q Did your colleagues at Greylock McKinnon not comment on your draft report?
A Again, I think that's a mischaracterization.
Q Okay. So just tell me. This isn't too much of a mystery. I'm just trying to understand.
Did you share your report with your team at Greylock McKinnon so they could provide edits to it and comment to it?
A Okay. So I wrote my report, and Greylock -- folks who work at Greylock McKinnon helped me fill in citations where I asked them to provide -- to identify full citations for certain types of facts. They helped me fill in specific numbers. They helped me construct certain exhibits,

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but I wrote my report. And they worked at my direction.
Q And then did you provide drafts to plaintiff's counsel to obtain comments from them about your report?
MR. HONIK: I'm sorry. I didn't hear the question. May I have it back, Jamie?
THE COURT REPORTER: Sure.
(Whereupon, the question was read back as requested.)
MR. HONIK: Thank you. It's a yes or no.
THE WITNESS: Yes.
BY MR. GOLDBERG:
Q Did anyone outside of Greylock McKinnon or plaintiff's counsel provide input to your report?
A No.
Q Did anyone at Boston University help gather information for your report?
A No.
MR. GOLDBERG: Can we pull up Tab 52? I'm gonna mark as Tab 52 Defendant's Amended Notice to Videotaped Deposition of Dr. Conti.
(Whereupon, Exhibit Conti 2 was marked

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for Identification.)
MR. HONIK: And we're calling that Conti 2?
MR. GOLDBERG: And this is going to be marked as Conti 2, yes.
BY MR. GOLDBERG:
Q Do you recognize this document, Dr. Conti?
A Yes.
Q Did you receive this document?
A Yes.
Q And this document, you understand, made certain document requests of you?
A Yes. I understand on Exhibit A, Page 3, or actually, Page 2, 3 and 4.
Q What did you do to respond to this set of document requests?
MR. HONIK: Dr. Conti, I have no objection to the question, but don't reveal discussions with counsel. It's protected by the work product privilege.
THE WITNESS: Thank you.
So there were 17 requests. They included my current up-to-date resume or CV. That, I worked on with Sarah Stone to get it to

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be updated, and then it was provided to counsel to provide to you.

Number 2 was a list of all articles, abstracts, studies, reports, seminar materials, presentations, publications or other writings authored or co-authored by me from 2022 to the present, that relate to the use of data after team members -- the use of pharmaceutical data --

Q Doctor. Doctor, I don't --

A Hold on.

Q Hang on. Hang on. Hang on.

MR. HONIK: Mr. Goldberg, let her finish, and then you can interject whatever --

MR. GOLDBERG: Hang on a second. It's not -- the answer is not responsive to the question. And also, we really don't need to waste -- just hang on, Doctor. We don't need to waste the time. I'm not asking you to read the request out loud. I'm not asking you to read it. My question was what did you do to respond.

MR. HONIK: Excuse me. Excuse me. Seth, respectfully, she is completely responsive to your question. It's within her

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province to answer it in whatever way she thinks is appropriate. To frame her response, she is going through each request and identifying what she did.

Now, I'd like her to complete her response which you cut off. If you'd like to sharpen your question in some way and perhaps give her an instruction, that's fine. I have no objection.

MR. GOLDBERG: That's fine.

MR. HONIK: But -- but she was in the middle -- she was in the middle of a response, which was highly responsive, even if it didn't satisfy what you wanted.

You can continue, Dr. Conti, and then pause.

MR. GOLDBERG: Objection. I'm withdrawing -- I'm withdrawing the question, so there's no reason...

MR. HONIK: That's fine. Very good. Thank you. Next question.

BY MR. GOLDBERG:

Q Did you -- did you collect any documents to respond to this request?

A Yes. That's what I'm trying to answer

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in specifics. So -- so there's a --

Q What did you --

A Hold on, please let me finish.

You requested 17 separate items, so in order to answer your question, I am happy to tell you, for each request, how I answered -- how I gathered documents and provided that information.

Q Okay. We don't have to do that. Okay. We'll -- we'll get to it.

MR. GOLDBERG: Can we pull up document 65, please?

BY MR. GOLDBERG:

Q Do you recognize the document that's on the screen?

A No.

MR. GOLDBERG: Marking as Conti 3, the document entitled, "Plaintiffs' Objections and Responses to Defendants' Notice of Videotaped Deposition of Rena Conti, Ph.D."

(Whereupon, Exhibit Conti 3 was marked for Identification.)

BY MR. GOLDBERG:

Q Is this the first time you're seeing this document, Dr. Conti?

A Well, let me look through in detail,

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please. I'm on Page 6. I think there are --

Q Yeah, my question was --

A -- 15 pages. You asked me if I had seen this, and I'm saying I'm going to look through.

Q We can go off the record while you do that.

MR. HONIK: Are you nearly done, Dr. Conti?

THE WITNESS: I'm on Page 8 now. If you can just give me a little bit more time.

MR. GOLDBERG: Let's go off the record.

THE VIDEOGRAPHER: The time is 11:29. We're going off the record.

(Whereupon, a short break was taken.)

THE VIDEOGRAPHER: The time is 11:30. We're back on the record.

BY MR. GOLDBERG:

Q Dr. Conti, have you seen this document before, what we've marked as Conti 3?

A No, I have not.

MR. GOLDBERG: Can you pull up -- the document -- the document that's Tab -- I believe it's Tab 0. Do you have a copy of your report handy? If not, there's one in the

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binder.
A I didn't hear you with it.
THE COURT REPORTER: I didn't hear you.
Q Your report is the first document in Binder 1. Do you have -- get that unless you have a copy of it handy.
A I have Tab 1 in front of me.
Q Okay. Actually, before we get to that --
MR. GOLDBERG: And that can come down, sorry about that.
Could you please pull up document 70 -- I'm sorry, not 70, document 67.
THE VIDEOGRAPHER: This will be Exhibit 4?
MR. GOLDBERG: This will be, yes.
THE WITNESS: I'm sorry. Did you say 64?
MR. HONIK: 67.
MR. GOLDBERG: Document 67, which we are marking as Exhibit Conti 4.
(Whereupon, Exhibit Conti 4 was marked for Identification.)

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BY MR. GOLDBERG:
Q Do you recognize document -- the document we have marked as Conti 4?
A No.
Q I'll represent to you that these were the invoices of Greylock McKinnon Associates that were provided in response to the document request. Do you have any reason to disagree with that representation?
A No.
Q And you can see that this is -- at least on the first page, you can see it's an invoice submitted to Conlee Whitely and David Stanoch. Okay. Do you see that?
A Yes.
Q And those are plaintiffs' counsel in this case, right?
A That's my understanding, yes.
Q I just want to ask you about a few of the invoices here, some entries on these, just so we can understand. It looks like -- looking at the first page, and I do believe these are in chronological order. It looks like you first started working on this back in January of 2020. Is that more or less correct?

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A Right. I think winter 2020 is when we first started having discussions, like I said, before the pandemic.
Q Yeah. Okay. Yeah. I know earlier you said February, March, but it looks like it was more like January that you got into this matter; is that correct?
A Well, that's what it says here, so must be.
Q And just going through -- at the time, it looks like your hourly rate was $675 an hour if we go to that column. And you said that your hourly rate is different now?
A Is that a question?
Q Well, I'm trying to -- do you know what your hourly rate is now? It looks like if you go three or four pages in --
A Yeah.
Q What is your hourly rate now?
A I think it's either 750 or 775. I think it has changed a little bit over time.
Q Okay. We'll get there, but it is 775.
Let's just go down this -- let's just go through this so we can get some names here. Who is -- after -- so you have four entries for

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Dr. Conti in 2020. And who is the next person?
A Mike Augusteijn.
Q What did Mike do?
A It says that he discussed --
Q Okay. What -- what does -- what did Mike do on the -- not in this particular entry. What did Mike do for the project?
A Mike is also an expert on data and --
THE COURT REPORTER: And what?
THE WITNESS: Data, acquisition in cleaning, in manipulation, in analysis. And so I would expect that he would have worked on this in that capacity.
BY MR. GOLDBERG:
Q Going to the next person, Bennett Erickson?
A Correct.
Q What did Bennett Erickson do, generally, for the project?
MR. HONIK: Objection, asked and answered.
THE WITNESS: Right. So I've already answered --
MR. GOLDBERG: I'm sorry.
THE WITNESS: So --

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BY MR. GOLDBERG:
Q I can withdraw the question. I'm sorry. You did talk about Bennett before.
The next person is Brian Hebert. What did Brian do for the project, generally?
A So it looks here that he billed time for import checking of manufacturing data.
Q Do you know what -- what manufacturing data he looked at?
A I don't.
Q Do you know what -- what is meant by the phrase "manufacturing data"?
A I'm assuming it was data that was related to the sale of these products.
Q That's pretty broad. Do you -- is there any particular data that you think he looked at related to the sale of the products?
A I don't know.
Q If you go on into 2021, now you've got Sarah Honan added to the invoices. Who is Sarah Honan? Is that the Sarah we mentioned earlier? No, that was Sarah Stone.
A Right, Sarah Stone. So Sarah Stone and Bennett Erickson are the people that I have been working with at GMA on this matter. There are a

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handful of other people that generally support Bennett and Sarah that I don't know as well. So Sarah Honan is -- is one of those people.
Q Do you know -- can you describe, generally, what she did for the project?
A It says here "Imported IQVIA data."
Q If you -- on the third page of the document, assuming you have double-sided copies, it's -- it's invoice 21158.
A Yes. That's not what's on the screen, but I see -- I am on that.
Q Okay. The first entry for Bennett says, "Work on valsartan cGMP market share analysis."
What -- do you know what that means?
A I'm sorry, I'm a little confused, because what's on the screen is not -- I don't think what we're talking about, so can we just make sure we're on the same page?
So invoice 21158, is that what we're talking about right now?
Q Right.
A Okay. Good. So --
Q The question is, Bennett says he worked on valsartan cGMP market share analysis.

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What -- what was that?
A I don't know.
Q You don't know what he meant by "cGMP market share analysis"?
A I'm assuming it has something to do with -- there are multiple manufacturers of these products at issue in this matter. But I don't know what he specifically meant on this date.
Q Do you know if Bennett's cGMP market share analyses were produced in this case?
A I'm sorry, what do you mean by "produced"?
Q Provided to plaintiffs' counsel for production in this case.
A You mean did Bennett turn those documents over to you?
Q Well, did Greylock McKinnon or Bennett provide them to plaintiffs' counsel to produce in this case?
A Well, I'm assuming -- so I -- I mean, the short answer is I don't know. The longer answer is by definition, my report contains the sales of these products across different manufacturers over time. And so I'm assuming that it's related to what Bennett states here, and those -- all of that back

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up and -- have been produced. They are part of my report.
Q Did you rely on a market share analysis in reaching your report -- in reaching your opinions?
A Again, by definition, the at-issue products are valsartan drugs made by different manufacturers. My report had to identify those manufacturers in national data and then apportion sales of those products across different manufacturers.
If you go further down on the fourth line, Bennett says, "Work on review of repackager NDCs. Create comparison of FDA-recalled" --
COURT REPORTER: I'm sorry, Doctor. Bennett says, "Work on review of..."
THE WITNESS: "Repackager NDCs. Create comparison of FDA-recalled NDCs to IQVIA NDCs."
I think that -- so -- so there is an FDA list of recalled valsartan products, and -- that identifies products by NDC code in the IQVIA data. I can identify products by NDC code, but products are very commonly repackaged and relabeled by private label -- by private

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label distributers and even retailers such as CVS or Costco.

And so in order to go from the NDC list produced by the -- by the FDA to Xponent was actually sold into the U.S. market, there is -- there is a job that needs to get done. Because repackagers or relabelers will change the NDC code by definition.

And so there was work that was done to match NDC codes or drugs at issue in this matter with the national sales that we had on these products. All of that was produced in my report.

BY MR. GOLDBERG:

Q Let's just start at the beginning of this. And if you go back to the first page of this document, do you see it says, for you, Dr. Conti --

THE COURT REPORTER: I'm sorry, Seth. Can you start that again?

BY MR. GOLDBERG:

Q It looks like you invoiced two hours, 2.6 hours; is that correct?

A Yes, I see that here.

Q And if you go along with me to the next invoice, there's -- there's no entry for

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Dr. Conti; am I correct?

A You mean -- again, I don't know --

Q Invoice --

COURT REPORTER: All right. I cannot -- I can't take both of you down at the same time. And you're both interrupting each other, and so you're not giving me a chance to do my job.

MR. GOLDBERG: Okay. Let's not worry about the screen since you have the binder in front of you, and that was the purpose of giving you the document in hard copy. So can you -- and the tech can follow along if the tech can follow along.

BY MR. GOLDBERG:

Q Right now I'm looking at Invoice 21024, which is in your binder. Do you see that.

A Yes.

Q Okay. And there's not an entry for Dr. Conti in there, correct?

MR. HONIK: Seth, I think for the benefit of myself and all other counsel, can the tech bring up the specific document?

MR. GOLDBERG: Sure.

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MR. HONIK: Thank you.

MR. GOLDBERG: Sure.

MR. HONIK: I see it now. Thank you.

BY MR. GOLDBERG:

Q And then if we go to --

A It's two pages, actually. It's two pages.

Q Right. And there's no entry for Dr. Conti on that invoice, correct?

A Correct.

Q And then the next invoice is 21158. Do you see that?

A Yes.

Q And there's no invoice for Dr. Conti there? There's no time invoiced for Dr. Conti in that invoice, correct?

A Correct, but there is mention of me participating in calls with the attorney.

Q So you participated in that call on May 24th, 2021, right?

A Yes.

Q Let's turn to the next invoice, which is 21617. There we see Dr. Conti, you billed 12.75 hours, right? Correct?

A I'm just -- I didn't -- I didn't

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prepare this invoice, so I'm just looking through --

Q Sure.

A -- what is actually billed. That's correct.

Q And that invoice takes us through 12-29-21. It's the last date anyone billed time on that invoice. Do you see that?

A Well, it's the last time that some of the staff billed time on the invoice. I can see that.

Q Based on my review of these invoices, before December 29th, 2021, you billed, in total, approximately 15 hours for your work in this matter; is that a fair representation?

MR. HONIK: Object to form.

THE WITNESS: Well, again, I didn't produce these documents, so I just simply billed for the time that's listed here. But if there's a different process for what I submit and what GMA does in what is listed here if there is time, I'm happy -- that I billed, I'm happy to total it up. I haven't done that.

It looks like, in the first invoice, there's about two-and-a-half hours.

COURT REPORTER: There is -- there's

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what?
THE WITNESS: About two-and-a-half hours.
In the last invoice there's about 12, almost 13 hours. So I think that's fair. So there's approximately 15 to 16 hours that I billed for my time on these invoices.
BY MR. GOLDBERG:
Q Are there other Greylock McKinnon invoices that haven't been produced?
A So I am woefully behind in my time on this matter. I have a list of the time that I have worked on this, but it has not been completely submitted to Greylock McKinnon or to the attorneys.
Q But you were asked -- Greylock McKinnon was asked to produce your invoices in this case, and you didn't comply with that request?
MR. HONIK: Object to the form.
THE WITNESS: Of course I did.
BY MR. GOLDBERG:
Q Well, why don't we have that time and your invoices for that?
A You mean -- you mean all the invoices?
Q Yeah.

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A Because I'm really busy, frankly. I'm teaching intensely. I've been doing a lot of other work to support government activity. And I have a very sick mother that I am managing her time and also taking care of my kid. So I've been very, very busy over the past two months and --
Q Well, I'm not -- I'm not --
MR. HONIK: Don't interrupt her, please.
THE WITNESS: So I have been really, really busy, and so my time is not complete.
BY MR. GOLDBERG:
Q I'm not concerned about your time in 2022. You --
A I'm saying that my time in 2021, I spent the majority of 2021 dealing with a very sick mother, traveling in three separate cities and taking care of my child, in addition to myself, in addition to very intense teaching and other activities. I am behind in my time.
Q Were you able to put your time in for some invoices, but not others; is that what you're saying?
A What I'm saying is my mother became very sick last summer, and so my time -- and I was

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also teaching intensely during that time. I have actually been teaching intensely since July. And so I have been actively working on this case, but I have not submitted my time because I frankly did not have the time to do it.
Q Well, let's look at invoice 21617. That's the last invoice in the -- in the packet. That's your 2021 time. And --
A I'm sorry. I'm sorry. I'm not -- I'm not following you. Where are you?
Q It's up on the screen, invoice 21617. It's the last invoice in the packet.
A I can see that.
Q So you billed an hour in May of 2021, correct? You billed an hour in September 2021, correct? And -- am I correct?
A I can see that there.
Q And you billed 10.75 hours in October 2021, correct?
A Correct.
Q How much time do you expect to bill plaintiffs for 2021 in addition to these 12.75 hours?
A So I have a preliminary listing of my time, and it amounts to approximately 60 hours.

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Q And that's for 2021?
A Yes. Oh, 2021 and 2022.
Q And how much of that time is 2021 versus 2022?
A I would say the majority.
Q Is 2021?
A Correct.
Q How much time have you spent on this matter -- excuse me -- in 2022?
A In preparing for the deposition and doing a handful of other things, maybe about 20 hours or so. I don't have a specific accounting yet. Again, I've been going back and forth between Boston, New York, Philadelphia and Chicago, because my mother is really sick, for every single week since the new year.
Q Do you think you'd be able to provide that preliminary list to your counsel so that we can see it?
A Sure. I mean, my -- my plan is to -- to finish it. I don't like to submit bills, and I don't -- I don't like to submit bills that I don't feel -- that aren't triple checked, and so I have a process for doing that.
MR. GOLDBERG: Why don't we go off the

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record and take a five-minute break just to give everybody a minute?

MR. HONIK: Why don't we call it 10 minutes and come back at 10:07. Okay?

MR. GOLDBERG: Sounds good.

THE VIDEOGRAPHER: The time is 11:57. This ends Media Unit Number 1.

(Whereupon, a short break was taken.)

THE VIDEOGRAPHER: The time is 12:11. This begins Media Number 2, and back on the record.

BY MR. GOLDBERG:

Q Dr. Conti, if you could pull and put in front of you your report -- or your declaration, which we marked as -- which we are going to mark as Conti 5.

(Whereupon, Exhibit Conti 5 was marked for Identification.)

BY MR. GOLDBERG:

Q And I'd like to start at the beginning of your report.

A Just give me a second to get it.

Q Okay. Let's start at the beginning of your report. I'm going to ask you questions about it in different places, but I'd like to start just

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at Paragraph 1.

You said you were retained to provide opinions and calculations regarding the -- the injury and damages incurred by classes of consumers and end-payers in this matter.

By "this matter," you're referring to the amended economic class action complaint, which is at Footnote 1, correct?

A Yes.

Q I'm just going to remind you to speak up a little bit, or maybe the microphone needs to be turned up.

And by "injury in this matter" -- you use the phrase "injury" -- you're -- you're talking about an economic injury of this matter, correct?

A Correct.

Q And your damages -- you're not providing opinions on liability, you're providing opinions on damages, right?

MR. HONIK: Object to form.

THE WITNESS: I'm providing opinions on economic injury and damages.

BY MR. GOLDBERG:

Q You're not -- you're not -- you haven't reached an opinion as to -- well, strike

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that question.

Going to the next paragraph, you say, "I have been asked by plaintiffs' counsel to assume that the at-issue valsartan products manufactured and sold by the defendants" -- and I'm gonna go now to the bottom -- "were recalled" -- "that were recalled in 2018 and 2019 were adulterated and misbranded."

Do you see that?

A Yes.

Q What do you mean by "at-issue valsartan products"?

A The valsartan products that were listed in Footnote 3 and Footnote 4.

Q When you use the phrase "at-issue valsartan products," are you limiting that to valsartan products that contained NDMA or NDEA?

A No.

COURT REPORTER: I'm sorry?

THE WITNESS: No.

MR. GOLDBERG: Can we go off the record for one second?

THE VIDEOGRAPHER: The time is 12:16. We're going off the record.

(Whereupon, a discussion was held off

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the record.)

THE VIDEOGRAPHER: The time is 12:18. We're back on the record.

BY MR. GOLDBERG:

Q So when you're using the phrase "at-issue valsartan products" in Paragraph 2 of your declaration and throughout your declaration, you're -- you're including valsartan products that may not have contained NDMA or NDEA?

MR. HONIK: Object to form, asked and answered.

THE WITNESS: When I am referring to "at-issue valsartan products," they are the ones listed in Footnote 2 and Footnote -- I'm sorry -- Footnote 3 and Footnote 4 of my report.

BY MR. GOLDBERG:

Q Footnote 3 and Footnote 4 refer to recalled valsartan products, correct?

MR. HONIK: Object to form.

THE WITNESS: No, not solely. That's a mischaracterization. So Footnote 3 and Footnote 4 define at-issue valsartan products. And they include products manufactured by -- I'm going to say this, and it's -- I'm going to

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butcher the name -- Zhejiang Huahai, Teva, Hetero, Torrent, Mylan and Aurobindo. And it includes the valsartan products marketed under Diovan name and their generic equivalent and then marketed under the Exforge name and their generic equivalent during the time period 2020 -- 2012 through 2018.

BY MR. GOLDBERG:

Q So you are including in at-issue valsartan products all valsartan manufactured by those defendants between 2012 and 2018?

A Correct.

Q That paragraph at the end talks about -- it says that you -- you were asked to assume that those products were adulterated and misbranded. On what basis do you --

A I'm sorry. I'm sorry. I don't know -- what -- what do you mean by "at the end"?

Q Okay. If you look at -- if you look at the paragraph, it says, "I have been asked" --

A Paragraph 2, okay.

Q You were asked to assume that those products were adulterated and misbranded, correct?

A Correct.

Q On what basis were you asked to make

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that assumption?

A I'm sorry. I don't understand the question.

Q What were the -- what was the basis for the adulteration that you were asked to assume?

A My understanding is, that basis is outlined in the complaint, which I reference in the first paragraph of my report and also Footnote 1.

Q Was there any particular aspect of these drugs that made them -- that you were asked to assume made them adulterated?

A Again, the basis of adulteration and misbranding is detailed in the complaint. And the definition of "adulterated" and "misbranded" is also outlined in the complaint, and is also outlined in my report in later paragraphs.

COURT REPORTER: Is also outlined in my report...

MR. HONIK: In later paragraphs, she said.

COURT REPORTER: Thank you.

MR. GOLDBERG: Counsel, Counsel, there's no need for you to testify.

MR. HONIK: I'm not testifying. It's just that I heard her --

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MR. GOLDBERG: What you understand --

MR. HONIK: Excuse me. Excuse me.

MR. GOLDBERG: Counsel, don't interrupt. Don't interrupt.

MR. HONIK: I'm going to protect this record in every single way that I want to. And as a courtesy to Ms. Moskowitz, I simply heard a noncontroversial three words and offered them to her to move things along. Thank you.

MR. GOLDBERG: Counsel, what do you understand to be the -- the adulteration that you assumed?

MR. HONIK: I'm not -- I'm not here to answer your questions. If it's directed --

MR. GOLDBERG: I'm sorry. I'm sorry, Dr. Conti.

BY MR. GOLDBERG:

Q I'd like to -- I'd like you to explain what you under- -- what you assumed.

A So, again, the assumption of adulteration and misbranding is detailed in the complaint and cited in my Paragraph 1 and Paragraph 2 in Footnotes 1, 2, 3 and 4.

Q It's fair to say, since you assume those facts that are in that complaint, you didn't

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reach any independent determination about whether there was an adulteration, correct?

A Again, I was asked to assume certain facts about the adulteration and misbranding of valsartan products at issue in this matter.

Q So the answer to my question is yes, you didn't independently conclude that there was an adulterated drug?

MR. HONIK: Object to form.

BY MR. GOLDBERG:

Q You were asked to make that assumption?

MR. HONIK: Object to the form.

BY MR. GOLDBERG:

Q Correct?

A I was asked to make that assumption, correct, as outlined in the complaint and in the footnotes listed here.

Q If you go on to Paragraph 4 of your complaint -- of your report, sorry --

A That's okay.

Q The first few lines is where I'm looking. It says, "The adulteration derives from the defendant manufacturers' allowance of chronic and pervasive deficiencies in the manufacturing of

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at-issue valsartan products."
What did you mean by "chronic and pervasive deficiencies"?
A My understanding is that there were -- there are systematic failures of cGMP in the manufacturing of the at-issue valsartan products by the manufacturers.
Q What are those systematic failures that you're referring to?
MR. HONIK: Objection, asked and answered.
THE WITNESS: There -- there is -- my understanding is that there are -- there are many of them, and those are outlined in the complaint and also supporting FDA documents of cGMP violations that the manufacturers were cited for.
BY MR. GOLDBERG:
Q You wrote your report, correct?
A I did.
Q Okay. So when you wrote "chronic and pervasive deficiencies," what were you -- what were you documenting? What chronic and pervasive --
MR. HONIK: Objection, asked and answered.

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BY MR. GOLDBERG:
Q What chronic and pervasive deficiencies were you referring to?
MR. HONIK: Object to form, asked and answered.
THE WITNESS: The ones that are referred to in the complaint at issue in this matter.
BY MR. GOLDBERG:
Q Any others?
A No.
Q Could you -- I -- I should have done this before, but if you could look at Attachment B to your report, which is up on the screen, as well, this -- this -- this attachment says, "Materials relied upon." Did you prepare this attachment?
A My staff, under my direction, prepared this document.
Q And is it fair to say that these were the materials you relied upon in reaching your opinions?
A In addition to my expertise and my experience in this matter -- or my experience in this industry.
Q So there was a document that you

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looked at and relied upon in reaching your opinions, that's listed here; is that correct?
A I don't think that's accurate, because again, I am in -- as an expert in the regulation of the pharmaceutical industry, and in many other contexts, I have spent a lot of time thinking about the -- the requirements of manufacturers, that they need to meet, in order to meet cGMP, and also violation of cGMP. I have also spent a lot of time thinking about and thinking on adulteration and misbranding of products, generally, in this industry.
So again, it's -- the materials relied upon or the ones listed here are the most germane to this specific matter. But my experience is also germane. That's in Attachment A.
Q Okay. So my question was, the documents that you relied upon to reach your opinions in this matter, leaving aside your experience and your general knowledge, but the specific documents that you relied upon to reach your opinions in this matter, are set forth in Attachment B, correct?
MR. HONIK: Object to the form, asked and answered.

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THE WITNESS: I don't -- I mean, again, I don't quite understand the distinction you're making. So again, my expertise and experience in the regulation of this industry informs everything I do, including the opinions that -- and the calculations that I performed in this matter.
Attachment A provides my CV, which has an extensive list of things that I have published on this industry. But Attachment B is enumerating the materials that I specifically relied on in this matter. But I don't see how I could distinguish between my experience generally in this industry and the materials that I relied on.
BY MR. GOLDBERG:
Q Well, you just -- you did, because this document says, "Materials Relied Upon." So you're making a distinction between your CV and the materials that you relied upon, right?
A No, you are. No, you are. What I'm saying is my experience informs the materials that I relied upon, by definition. I mean, I -- I know a lot about cGMP and the regulation of the products --

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Q Did you --
A Hold on, please, if I can finish.
I know a lot about the regulation of these products in the U.S. market. But it's based upon my experience working on many different aspects of this market. And it's many different products. That informs the documents that were selected and thought about specifically or cited specifically in my report.
Q Did you review any deposition testimony in reaching your opinions?
A No.
Q Did you --
A As I -- hold on. As I understand it --
Q No. No. No. You answered the question.
A No. No. No. I didn't answer.
MR. HONIK: She has not finished her response. Do not interrupt the witness.
THE WITNESS: So, as I understand it, the reports that were produced that mention my report, none of those people had been deposed yet. So I would have liked to have seen their depositions, because some of it -- what they

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say in the reports is confusing. But I have not -- my understanding is they have not been deposed yet.
BY MR. GOLDBERG:
Q Did you review any depositions of any witnesses in reaching your opinions in this case?
A No. I mean, some of -- like I said, the ones that I would have liked to have reviewed, I wasn't able to because they haven't been deposed yet.
Q So you haven't read a deposition of a plaintiff in this case?
A No.
Q Or a plaintiff --
A I understand that the depositions haven't been done of the economic experts.
Q I'm asking you about the plaintiffs. I'm not asking you about experts. You haven't read a deposition of a plaintiff in this case, correct?
A I have not.
Q You haven't read the deposition of a class representative in this case?
A I have not.
Q And you haven't read -- read the deposition of any defendant witnesses or employees

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in this case?
A My understanding, again, of the defendant experts in this case is that they have not -- they've produced reports, but they have not been deposed yet. So I don't see how I could read a deposition if it hasn't occurred yet.
Q If you go back in your report to Paragraph 4 --
A I'm sorry. I didn't hear you. I can't hear you.
THE COURT REPORTER: Seth, I can't hear you either.
MR. GOLDBERG: Sorry about that.
BY MR. GOLDBERG:
Q The third line refers to "a failure by the defendant manufacturers to implement quality assurance practices."
Do you have any specific understanding of what those quality assurance practices were?
MR. HONIK: Objection, asked and answered.
THE WITNESS: So manufacturers who are legally allowed to supply products to the pharmaceutical U.S. chains are required to attest to a very significant number of quality

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assurance practices, which include but are not limited to the risk, assessment and mitigation of their -- of their product from end to end. And there's also attestation of the practices that the firms are required to provide to the --
THE COURT REPORTER: To the -- I'm sorry. To the what?
THE WITNESS: Are required to provide to the U.S. Food and Drug Administration, upon their initial application to get a license to sell these products to the U.S. market, but also over time. Yes, that's what I mean by "quality assurance practices."
BY MR. GOLDBERG:
Q Do you have any particular instances of quality assurance practices or the failure to implement quality assurance practices as to any of the defendants in this case?
MR. HONIK: Object to form and asked and answered.
THE WITNESS: Yes. They are detailed in the complaint, and they are also detailed in the FDA documents that are listed in -- detailing for each one of the defendants on the

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systematic --
THE COURT REPORTER: On the systematic --
THE WITNESS: And pervasive quality assurance.
COURT REPORTER: Excuse me, Counsel. One second. Let me see if I can turn my volume up.
THE VIDEOGRAPHER: Mr. Goldberg, I think the -- the paper shuffling may be distracting a little bit.
THE WITNESS: Correct. It's very hard to hear.
COURT REPORTER: Okay. I put my volume up.
BY MR. GOLDBERG:
Q Did you review any document that -- that detailed for you a failure to implement quality assurance practices by the defendant manufacturers?
MR. HONIK: Object to form, asked and answered.
THE WITNESS: Yes. The complaint details systematic and pervasive deficiency in -- in the cGMP. And then there are FDA documents that are supportive of that for each

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of the defendant manufacturers that details many different deficiencies in cGMP.
BY MR. GOLDBERG:
Q Which FDA documents --
A Hold on. In the manufacturing of these products.
Q Which FDA documents are you referring to?
A Hold on a second. We were just looking at the materials relied upon. I think it's in Attachment B.
So there's the complaint and then -- and -- I don't see it assessed here, but I have a binder of FDA documents that are specific to each one of the manufacturers that I have reviewed that are related to the at-issue products here.
Q What binder are you referring to?
A I'm happy to get it if you can just give me a second.
MR. GOLDBERG: Let's go off the record.
THE VIDEOGRAPHER: The time is 12:42. We're going off the record.
(Whereupon, a discussion was held off the record.)

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THE VIDEOGRAPHER: The time is 12:42. We're back on the record.
BY MR. GOLDBERG:
Q I want you to listen to the questions I'm going to ask. I just want to you answer the questions I'm going to ask. Okay?
The binder that -- the binder that you have in front of you now --
A Correct.
Q -- you did not provide that binder to your counsel before today, correct?
MR. HONIK: Object to the form of the question.
THE COURT REPORTER: What was your answer?
THE WITNESS: I mean, I did not -- I, me, provide it. It's the complaint and the backup and some of the documents listed in the complaint. The complaint is listed in my Attachment B, and the documents that are related specifically to inspection reports, FDA, failure notices to the -- to each of the manufacturers are just the complaint. They're just the backup to the complaint.

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BY MR. GOLDBERG:
Q Okay. I understand.
So you're saying you looked at the complaint and the exhibits to the complaint?
A Correct.
Q That's what is in that binder?
A Yes. And specifically, I reviewed the -- the backup material that the complaint references related to the systematic and persuasive [sic] failures of cGMP for each of the defendants.
So I'm gonna say this incorrectly again, Zhejiang Huahai --
Q You don't have to -- you don't have to name the defendants. We know who they are.
A Okay. No, I'm just telling you -- I'm saying to you, not the defendants, but for the specific documents related to cGMP violations, the products that I looked -- the manufacturers that I looked at were Zhejiang --
MR. HONIK: You can say ZHP. ZHP.
THE WITNESS: ZHP. Thank you.
ZHP and the FDA warning letters related to that. Mylan, in multiple ways, and Aurobindo, Torrent, Hetero and Lantech.

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THE COURT REPORTER: What was the last one?
THE WITNESS: And Lantech.
BY MR. GOLDBERG:
Q Yes or no, the documents that you relied on for the pervasive deficiencies that you referred to, are the complaint and the exhibits attached to the complaint?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: Okay. So I have answered your question a bunch of times. So again, there's --
MR. GOLDBERG: I'm going to strike the -- I'm going to withdraw the question. Counsel, we're going to off the record.
THE VIDEOGRAPHER: The time is 12:46. We are going off the record.
(Whereupon, a discussion was held off the record.)
MR. HONIK: Let's proceed on the stenographic record. Are we off the video record?
THE VIDEOGRAPHER: We are off the video.

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MR. HONIK: Okay. Before we go back on the video, is there anything else you need to say, Seth? I don't want to waste more time.
MR. GOLDBERG: Well, you want me to put it on the record, so I'm going to.
MR. HONIK: That's fine. Do you want it on the video record?
MR. GOLDBERG: Sure.
MR. HONIK: Okay. Queue us, please, Justin.
THE VIDEOGRAPHER: The time is 12:48. We're back on the record.
BY MR. GOLDBERG:
Q Let's turn to Paragraph 23 of your report. In this paragraph, you refer --
A Hold on. I'm not there yet. Hold on. Paragraph 23 or Page 23?
Q Paragraph 23.
A Great. Thank you. Okay. Just give me one second.
Q In this paragraph --
A Just give me -- just give me one second. Okay.
Q In this paragraph, you're referring to reasons the FDA deems a drug as misbranded. Do you see that?
A Yes.
Q Were there any particular reasons that you were asked to assume that are listed here?
MR. HONIK: Object to the form of the question.
THE WITNESS: All of them. So the -- my -- I was -- hold on.
MR. HONIK: She's responding to your question. Please stop interrupting her.
THE WITNESS: So I -- thank you.
I was asked to assume these products were misbranded. This paragraph, Paragraph 23 in my report, lists the definition of "misbranding" according to the Food and Drug Administration. And the definition is inclusive.
BY MR. GOLDBERG:
Q So you were asked to assume that all of these particular reasons that a drug can be misbranded applied to the valsartan in this case?
MR. HONIK: Objection to form.
THE WITNESS: That is -- that is a mischaracterization of my testimony. I was asked to assume that these products at issue were misbranded. And paragraph 23 is providing a definition by the FDA of what "misbranded" means.
BY MR. GOLDBERG:
Q And my particular question is, were you asked to assume that any of these particular reasons occurred with respect to the at-issue valsartan products?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: I was asked to assume that the at-issue valsartan products were misbranded. "Misbranded" is defined by the U.S. Food and Drug Administration in a very particular way. And that definition is provided in Paragraph 23 of my report.
BY MR. GOLDBERG:
Q Looking at Paragraph 23, which of these specific reasons for misbranding do you believe applied in this -- with respect to the at-issue valsartan products?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: The complaint uses the term "misbranded." From the perspective of

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regulation of pharmaceutical industry, there is a particular definition of misbranding that the U.S. Food and Drug Administration uses. My understanding, and what I was asked to assume, is that the term "misbranded" is specific to the U.S. Food and Drug Administration's definition. And the definition is listed here and is inclusive.

BY MR. GOLDBERG:

Q You -- you understand that a misbranding can occur for any one of these reasons, right?

A Again, I was asked to assume that these products were misbranded.

The definition of "misbranding" by the U.S. Food and Drug Administration is provided here, and it's inclusive.

Q So you don't agree with my question? You don't agree that any one of these that are listed in 20 -- in Paragraph 23 could be a reason for misbranding?

MR. HONIK: Object to form, asked and answered.

THE WITNESS: Okay. The FDA has a very specific definition of "misbranded." It

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is stated here. In my Paragraph 23 of my report, it says, "Reasons that the FDA deems a drug as misbranded include, but are not limited to:" and then it enumerates the specifics. I'd be happy to go on and provide those specifics --

BY MR. GOLDBERG:

Q So I'm asking you --

MR. HONIK: Don't interrupt the witness. Don't interrupt the witness.

BY MR. GOLDBERG:

Q I would like you to --

MR. GOLDBERG: I'm not interrupting her.

MR. HONIK: Do not interrupt the witness.

BY MR. GOLDBERG:

Q I would like to you answer my question.

MR. HONIK: If you persist in interrupting the witness in the middle of her responses, we will conclude the deposition. She was in the middle of her response.

Ms. Moskowitz, can you please read back the question and the answer?

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MR. GOLDBERG: No. Counsel --

MR. HONIK: No.

MR. GOLDBERG: Counsel, let me just say that you -- you are interfering with this deposition, and the witness is clearly filibustering. And we will -- we will not continue with this. Judge Vanaskie has been very clear that he will not permit filibustering by witnesses, period. He's actually sanctioned witnesses for it. And if we have to do it, we will get him on the phone for this.

I tried to do this with you off the record, but you refused. I tried to do this in a way that would not color the testimony, but you did not want to do that. You wanted it on the record. The reality is, as the last five questions will demonstrate, this witness is filibustering and not answering the questions that are being asked. Period.

MR. HONIK: It seems to me with the last five questions --

MR. GOLDBERG: If you want to continue in this way, we will conclude the deposition with a call to Judge Vanaskie.

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MR. HONIK: What the last five questions and responses revealed to me is your ignorance in understanding the witness, full stop. We will not proceed until and unless you allow the witness to complete her responses, even if you don't like them.

Accordingly, I will ask the reporter to read the pending question and as much as Dr. Conti's response as she has so that she may complete her response. And then you should feel free to ask another question.

Ms. Moskowitz?

COURT REPORTER: Sure.

(Whereupon, the answer was read back as requested.)

MR. HONIK: Do you wish to complete your response, Dr. Conti, or have you lost your train of thought?

THE WITNESS: I have not lost my train of thought, but I don't have to...

So, again, I was asked to assume that these products were misbranded. "Misbranded" from the FDA's perspective has its very specific definition that's enumerated -- that's listed in Paragraph 23. And that -- that

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definition of "misbranded" is inclusive.
BY MR. GOLDBERG:
Q Let's try it like this: Which -- which of these enumerated factors of misbranding apply to the at-issue products -- the at-issue valsartan products?
MR. HONIK: Objection, asked and answered and outside the scope of her report.
You may respond.
THE WITNESS: I was asked to assume these products were misbranded, and -- and again, that the definition of "misbranded" was inclusive of all, but -- but not limited to these factors.
BY MR. GOLDBERG:
Q So you weren't asked to assume any particular fact -- any particular reason for misbranding. You were just asked to assume misbranding based on the definition of "misbranding"?
MR. HONIK: Object to form, asked and answered.
BY MR. GOLDBERG:
Q And --
COURT REPORTER: I'm sorry. I didn't

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hear a response.
THE WITNESS: Correct.
COURT REPORTER: Thank you.
BY MR. GOLDBERG:
Q And if you -- if you look at the -- the immediately preceding paragraph, Paragraph 22, you provide the reasons the FDA deems a drug adulterated, correct?
A I -- no. That is not what the paragraph states. The paragraph states the reasons the FDA deems a drug adulterated to include, but not be limited to factors that are listed here.
Q And is the same true with respect to adulteration, that you were asked to assume the drugs were adulterated based on the definition of "adulterated" as we see it here?
MR. HONIK: Object to form.
THE WITNESS: The FDA has a very specific definition of "adulteration," which is listed here, but again, it's inclusive. I was asked to assume that adulteration -- that the use of the term "adulteration" in the -- in the complaint is inclusive of these factors and the other factors that the FDA considers a product to be adulterated.

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BY MR. GOLDBERG:
Q So you were asked to assume the drugs were adulterated based on all of the different factors the FDA might consider a drug adulterated?
MR. HONIK: Object to the form.
BY MR. GOLDBERG:
Q Those listed -- those listed here and those that are not listed here?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: Again, I was -- so any one of these factors can make a product adulterated in the view of the FDA, just like any one of these factors could be considered -- would make a product misbranded, according to Paragraph 23 and -- and beyond.
I was asked to assume that these products are considered to be adulterated and misbranded according to the FDA's definition, which is inclusive of all of the factors listed, both in my report and alluded to -- and alluded to as additional.
BY MR. GOLDBERG:
Q Let's turn back to Paragraph 6 of your report. It's on Page 3 of your report.

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Here you say -- and I'm looking in the middle of the paragraph -- "Prescription drugs that are adulterated and misbranded are neither recognized by the United States government as legitimate products to be sold by manufacturers nor paid for by payors; nor are they considered legitimate products by the pharmaceutical industry."
What do you mean by "legitimate products"?
A I mean that a product that does not meet cGMP regulations cannot be entered into the legal class of trade into the United States pharmaceutical trade. That means that pharmacies can't sell products that don't meet cGMP practices and standards, and nor can -- and nor do payors pay for product --
COURT REPORTER: And nor do payors...
THE WITNESS: Pay for products that do not meet cGMP.
BY MR. GOLDBERG:
Q Is it -- is it the fact that there's a cGMP violation that makes the product not legitimate, or is it the fact that, as you put it, pharmacies wouldn't pay for it, that consumers wouldn't pay for it? What makes the product not

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legitimate?
MR. HONIK: Object to form, asked an answered.
THE WITNESS: Violation of cGMP.
Remember -- and -- and also just to make sure that I understand your question, payors pay for products, consumers and insurers, right? Pharmacies may stock products for sale.
BY MR. GOLDBERG:
Q Is it your understanding that any cGMP violation would make a product not legitimate?
MR. HONIK: Object to form, outside the scope of her report.
You may answer.
THE WITNESS: Manufacturers must attest to their compliance with cGMP practices in order to enter their products into the U.S. class of trade and then throughout the pharmaceutical supply chain, both as a condition of sale into the U.S. and then yearly.
BY MR. GOLDBERG:
Q Okay. Is it -- is it your understanding that any cGMP violation would make the

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product not legitimate?
MR. HONIK: Object to form.
BY MR. GOLDBERG:
Q In your view?
MR. HONIK: Object to form, asked and answered, beyond the scope.
THE WITNESS: So, again -- again, my understanding is that pharmaceutical manufacturers that want to sell their product into the closed pharmaceutical chain in the United States must attest that their products meet cGMP. But when they first enter and launch into the market, that's a conditional on launch -- that their launch is conditional on that attestation. And then annually thereafter.
THE COURT REPORTER: And then annually, they're...
THE WITNESS: Thereafter.
COURT REPORTER: Okay.
BY MR. GOLDBERG:
Q So it's your testimony that any cGMP violation would make a product not legitimate?
MR. HONIK: Object to the form, asked and answered.

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THE WITNESS: That is not my testimony, sir.
BY MR. GOLDBERG:
Q So a product that has a cGMP violation could be a legitimate product, in your view?
MR. HONIK: Object to the form, asked and answered, beyond the scope.
THE WITNESS: Again -- thank you.
Again, pharmacy manufacturers cannot enter their products into the U.S. -- the closed U.S. chain of pharmaceutical products sold, bought, insured, consumed and -- by pharmacies, et cetera, if they do not meet cGMPs both upon launch -- they can't actually enter the U.S. market, and they can't sell over time unless they make the attestation that their products are cGMP compliant.
BY MR. GOLDBERG:
Q Is it your testimony that products produced by a manufacturer where there are cGMP violations cannot be sold in the U.S.?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: Okay. Again, a pharmaceutical manufacturer cannot --

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BY MR. GOLDBERG:
Q My question is a yes or no question.
MR. HONIK: You're interrupting the witness.
MR. GOLDBERG: I am because my question is yes or no question.
MR. HONIK: The witness is permitted to answer it in whatever manner she believes is appropriate. You have interrupted her.
MR. GOLDBERG: Actually -- actually, that's not what happens under the rules in this case. If it's a yes or no question, the witness should say yes or no and then qualify their answer if need be.
MR. HONIK: Yeah. Whatever you believe is -- is fine, Seth. You're not to interrupt her. If you persist in interrupting her, then we'll have to stop the deposition. But as far as I can see, you have asked her the same question a half dozen times. She's -- she's being quite level with you in responding. I'm protecting the record.
Madam reporter, let's have the question, and we'll have Dr. Conti answer it again.

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(Whereupon, the question was read back as requested.)
MR. HONIK: And then I've noted my objection.
You can respond, Dr. Conti.
THE WITNESS: Thank you.
Pharmaceutical manufacturers are not allowed to sell their products into the U.S. without meeting cGMP standards both upon their launch and over time. And just to be really clear, it is -- from -- from the U.S. regulator's perspective, it is on the manufacturer to ensure and to attest that they are manufacturing their products to the gold standard of cGMP that is -- as outlined by the U.S. Food and Drug Administration.
BY MR. GOLDBERG:
Q Is it -- do you -- is it your view that -- is it your understanding that any cGMP violation would prevent a manufacturer from selling the product in the case -- in the U.S.?
MR. HONIK: Object to form, asked and answered and beyond the scope.
You may respond.
THE WITNESS: Again --

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MR. GOLDBERG: When you say "beyond the scope" -- can I just get a clarification counsel? When you say "beyond the scope," what do you mean?
MR. HONIK: Happily. You've established that Dr. Conti was retained to provide opinions and calculations regarding the injury and damages incurred by classes of consumers and end-payors in this matter.
To do so, she was assigned -- she must assign an economic value to prescription drugs that were adulterated and misbranded, two terms that she's now defined for you, as outlined in the complaint. As such, she's not our cGMP expert. We have such an expert. He's been deposed. And I'm merely pointing out to you that if you want to drill down on cGPM standards beyond what Dr. Conti, as a health economist, needs to know, I think you're wasting time.
But more importantly, it's beyond the scope of her expertise and her report, which you, yourself, established about two hours ago.
That's the basis for my objection when I say "beyond the scope." Let's proceed.

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MR. GOLDBERG: Why don't we --
THE WITNESS: I think there's a pending question. Would you like me the answer it?
MR. GOLDBERG: No, I will withdraw that. I can withdraw that question.
THE WITNESS: Okay. May I ask -- I'm not sure what time it is in the real world.
MR. HONIK: It's 1:12 p.m. Is this a good time to break for lunch, Dr. Conti?
MR. GOLDBERG: Sure.
THE WITNESS: That would be great. Thank you.
MR. HONIK: And for your comfort, how much time would you like?
THE WITNESS: Can we have half an hour, please?
MR. HONIK: Yes. So we'll resume at 1:45.
THE WITNESS: Thank you.
THE VIDEOGRAPHER: The time is 1:13. This ends Media Unit Number 2. We're going off the record.
(Whereupon, a lunch recess was taken.)
THE VIDEOGRAPHER: The time is 1:53.

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This begins Media Unit Number 3. We're back on the record.
BY MR. GOLDBERG:
Q Dr. Conti, if you look at Paragraph 6 of your report --
A Just one second. Let me get it. Okay.
Q The last sentence in this paragraph, you use the phrase, "non-product status." What do you mean by "non-product status"?
A Only prescription drugs -- only products that have met the evidentiary standard for cGMP, in addition to safety and efficacy, are allowed to be sold into the U.S. market trade.
So products that do not meet that standard of being manufactured to good manufacturing practices -- or according to good manufacturing practices, plus are safe and efficacious, are allowed to be sold into the -- into the U.S. product market. Those that do not meet that standard are not -- are not -- according -- according to the U.S. Food and Drug Administration, would be not allowed.
Q When you use the terms "safety" and "efficacy," can you explain what you mean by the

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term -- by each of those terms?
A All right. Again, this is a -- this is one of the most highly regulated consumer product markets, and so the FDA has very specific definitions of "safety" and "efficacy."
What I mean here is that the product is judged to be safe and efficacious according to the U.S. Food and Drug Administration's rules.
Q You don't have an independent understanding of safety and efficacy? It's just based on what the FDA would determine to be safe and effective?
MR. HONIK: Object to the form.
THE WITNESS: For my purposes in this report, correct. The definitions I'm using of safety and efficacy and meeting cGMP are those that relate to the Food and Drug Administration's definitions.
BY MR. GOLDBERG:
Q If you scroll down -- or if you go down to Paragraph 7 -- I know you have a hard copy in front of you. The last sentence of this paragraph, you say, "Prescription drugs that are adulterated and misbranded have no economic value. They are worthless."

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What do you mean by "worthless"?
A I mean this is in --
COURT REPORTER: You mean this in...
THE WITNESS: Thank you.
I mean this in -- in economic sense, that there is no legitimate supply curve of products -- of products that do not meet the standard of cGMP in addition to being --
THE COURT REPORTER: In addition to being...
THE WITNESS: Judged safe and efficacious by the Food and Drug Administration.
BY MR. GOLDBERG:
Q Is it -- is it your view that there's no degree of adulteration when it comes to worthlessness and that all adulterated drugs, for any reason, are worthless?
MR. HONIK: Object to form.
THE WITNESS: So my understanding is that in order to be allowed to be sold into the U.S. supply chain of prescription drugs, the manufacturer needs to attest that these products are manufactured according to cGMP, at minimum, and in addition, are safe and

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efficacious as -- as attested to in the drug's manufacturing report to the Food and Drug Administration.
BY MR. GOLDBERG:
Q So products that have such an attestation have value, right?
MR. HONIK: Object to form.
THE WITNESS: You mischaracterized my testimony.
BY MR. GOLDBERG:
Q I'm asking you a question. Products that have the attestation you described have value, correct?
MR. HONIK: Object to form.
THE WITNESS: Okay. Again, prescription -- pharmaceutical manufacturers are not allowed to sell products into the U.S. market that are not produced in a manner of cGMP compliant, plus are safe and efficacious as judged by the Food and Drug Administration.
There is a long and very complicated route for a product to be judged, a drug, a prescription drug, that is allowed to be entered into the U.S. class of trade. Manufacturers have to meet all of those

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standards, both in terms of attestation -- in other words, they can say these things, but they -- but they are also judged by the regulator itself about whether or not these things are actually --
THE COURT REPORTER: Are actually...
THE WITNESS: True.
BY MR. GOLDBERG:
Q So products that are sold with that attestation have value?
MR. HONIK: Object to form, asked and answered.
THE WITNESS: Okay. Again, it's not just the attestation that matters. The U.S. regulator requires that any products that want to be sold into the U.S. market that is going to be considered a prescription drug, must be produced in accordance with cGMP and be safe and efficacious. And the manufacturer just -- can't just say that. They actually have to prove it to the regulator.
It is in that meaning that I mean that those products have value. In other words, products that -- I can say it in a different way, which is products have value. There is a

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legitimate supply curve if and only if they are produced according to cGMP and are safe and efficacious, both by attestation and by proof -- by empirical proof.
BY MR. GOLDBERG:
Q If the FDA is permitting those products to be sold, they have value?
A For prescription drugs, drugs that are actually called "drugs" by the Food and Drug Administration, they -- and are sold at pharmacies, and dispensed to American patients by physicians or by pharmacy chains, those products must meet the evidentiary standard of, they are produced according to cGMP, they are not adulterated or misbranded, and they are safe and efficacious, for the -- for the disease -- specific indication that the Food and Drug Administration approves that product for.
COURT REPORTER: I'm sorry. The Food and Drug Administration...
THE WITNESS: Approves that product to be sold for or used for.
BY MR. GOLDBERG:
Q So if the FDA has permitted -- if -- permitted prescription drugs to be sold at

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pharmacies, you would agree that those drugs have a value?
MR. HONIK: Object to form, asked and answered.
THE WITNESS: Well, wait. So it's not just that. So again, according to the regulator, a prescription drug is not allowed to enter into the U.S. class of trade, sold to a consumer, covered by a manufacturer -- or by an insurer, unless they meet the evidentiary standard of -- of being produced in accordance with cGMP at a minimum, and meet other requirements, as well.
BY MR. GOLDBERG:
Q Are you aware of any instance where a drug was sold, but it did not meet the minimum, as you put it, cGMP requirements?
A Again, drugs cannot enter into the U.S. class of trade without meeting the evidentiary standard. What I mean by that is the FDA will not approve a drug to enter into the U.S. class of trade without meeting the evidentiary standard and the manufacturer attesting that they are meeting that standard.
It is actually on the manufacturer --

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hold on. It's actually on the manufacturer to ensure that that product is what it says it is on the product's -- on the product's label.
BY MR. GOLDBERG:
Q Okay. So you -- you seem to be emphasizing the word "enter." Is there some particular emphasis you're putting on that?
A I don't -- I'm not sure what you mean by that question.
Q You keep saying the FDA will not allow -- a manufacturer cannot -- you -- you -- what you said is drugs cannot enter into the U.S. class of trade without meeting the evidentiary standard. What do you mean by "enter into the U.S. class of trade"?
A I mean they are not allowed to be sold into the U.S. market without meeting the evidentiary standard of being produced, at minimum, by cGMP and meeting other evidentiary standards, as well.
Q So what are the evidentiary standards that you're referring to? You have cGMP violations.
A I'm confused.
Q You used the phrase "evidentiary standard" in the four -- in your last four answers. What are the evidentiary standards you're referring

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to?
MR. HONIK: Object to form, asked and answered and beyond the scope of her report.
THE WITNESS: Okay. So you can look at Paragraph 6 of my report, "Federal law, as codified by regulations of the Food and Drug Administration, mandates that prescription drugs be produced in accordance with cGMP to ensure that the drugs meet the legal requirements of safety and that they have the quality, purity, identity and strength they are represented to conduct."
That's what I mean by the evidentiary standard of being sold into the U.S. or being legitimate products.
BY MR. GOLDBERG:
Q Let's take each one of those. What do you understand the term "quality," as you've used it, to mean?
A Quality is a process, from the U.S. Food and Drug Administration's perspective, so the print is both what it says it is, but it's also manufactured in a process that is a quality manufacturing process that meets cGMP.
Q What do you understand the term

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"purity" to mean, as you're using it?
A I mean, again, it's in accordance with the Food and Drug Administration's definition of it. So purity, identity and strength are all the FDA's definition.
Q Okay. You're -- so you're -- when you're using the term, you're really -- you're just saying based on how the FDA defines these terms?
A Yes.
Q Correct?
A Exactly. Just like my use of the term "adulterated," my use of the term "misbranded," they are all related to the U.S. government's definition inclusive of how these terms are actually being -- being used.
Q How these terms are being written in the regulations, that's what you're referring to?
A Correct.
Q I still want to understand. If a drug -- if a prescription drug is being sold -- so there's a supply for it. And people are buying it, so there's a demand for it. Does it -- is it still worthless if it doesn't meet some of these evidentiary standards?
MR. HONIK: Object to form.

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THE WITNESS: My statement is one related to the supply curve, not the demand curve. By definition, there is no supply of drugs -- of product that do not meet the definition of a "drug" according to the Food and Drug Administration. In order for a manufacturer to sell a product that meets the definition of the term "drug," it must meet the evidentiary standards of meeting and attesting to the cGMP production and be safe and efficacious for the indicated use.
BY MR. GOLDBERG:
Q So the demand -- you're -- you're not considering demand in that analysis, you're focusing on --
THE COURT REPORTER: Can you repeat that question, please?
BY MR. GOLDBERG:
Q You're not considering demand in your analysis, you're focusing on the supply?
A In my analysis, I don't know what you mean by my -- "in my analysis."
Q You said, "My statement is related to the supply curve, not the demand curve. By definition, there is no supply of drugs."

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And I am just confirming. So you're not thinking about it in terms of demand, you're thinking about it in terms of supply?
A What is "it" in your question?
Q The -- the question of whether the drug is -- a drug is worthless?
A So, again, from an economic perspective, there is no legitimate supply curve for a product that is adulterated and misbranded. That is by statute. Consumers can demand products that are illegal or illegitimate, but they're -- but a pharmacy can't sell a product that does not -- for which the manufacturer has not met the evidentiary standard and have been approved by the U.S. regulator for use in that -- in that context.
Q Do you have any -- I don't see it here. Did you cite to any economic treatise for the notion that if there is -- there is no legitimate supply curve for a product that is adulterated and misbranded?
A This is one of the most -- one of the most highly regulated consumer product markets that -- that exists in the United States. U.S. is -- maintains the gold standard for quality of its prescription drug supply.

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Every pharmaceutical manufacturer that sells products through to pharmacies and ultimately to American consumers, knows what the rules are. The rules are they must meet the evidentiary standard of permitting to quality manufacturing and be safe and efficacious.
From an economic standpoint, that -- it is meeting those regulations that allow there to be a supply of a product. I don't need to -- you can't think about the supply curve of prescription drugs without understanding what the regulation is that allows them to be sold to the U.S. That's your -- that's actually health economics 101.
Q Well, I'm trying to understand which health economics 101 treatise or authority you're citing for the notion that -- because in your view, there's no legitimate supply curve, a drug is worthless?
MR. HONIK: Object to form, asked and answered.
I'm sorry. Please answer, Dr. Conti.
THE WITNESS: Thank you.
It's not my view. This is the U.S. regulator's perspective. The U.S. regulator does not -- does not view -- does not allow

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drugs to be sold into the U.S. market that do not meet the evidentiary standard. And it's prescription drug manufacturers themselves that have wanted that standard to be as it is.

And so I -- I mean, there's plenty of published literature that talks about this, the importance of the evidentiary standard to the supply of these products, and I cite some of that in my report. But every pharmaceutical manufacturer that is allowed to sell into the U.S. market knows what the standard is.

BY MR. GOLDBERG:

Q You're -- you're not answering my question. My question is what economic support do you have for the notion that, if there's no supply, the drug is worthless?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: This is economics 101. If you go -- I'm more than happy to show you the picture. But there can be no price for a product that does not have a demand curve meeting a supply curve. There is no economic price if there is no legitimate supply curve.

There are plenty of economic textbooks

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that explain that an economic price is related to both demand and supply, and its -- and, you know, its relationship to each other.

BY MR. GOLDBERG:

Q Was it -- there was an economic -- there was an economic price that was paid for valsartan between 2012 and 2018, right?

MR. HONIK: Object to the form. Are you asking if consumers paid for it, paid for this drug?

THE WITNESS: I don't understand what you're asking.

MR. GOLDBERG: Counsel --

BY MR. GOLDBERG:

Q I'm using your phrase, "economic price." There was an economic price paid for valsartan between 2012 and 2018, right?

MR. HONIK: Right. And our lawsuit seeks --

MR. GOLDBERG: Counsel, you're not -- counsel, don't testify. Don't interrupt. Let the witness answer the question.

MR. HONIK: You have now asked the same question six times.

MR. GOLDBERG: Counsel, don't --

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counsel, don't coach the witness. Don't interfere.

MR. HONIK: This witness needs to be heard --

MR. GOLDBERG: Counsel, don't say a word. The question is pending. Witness will answer without your interruption. If you want to say objection, you can say objection.

MR. HONIK: I will say as many words as I deem appropriate --

MR. GOLDBERG: If you want to say objection to form, say it, but don't --

MR. HONIK: I will protect the record in the manner in which I see fit.

MR. GOLDBERG: No. You will interfere with the record.

MR. HONIK: What I'm -- what I'm now trying to do, because I believe you've asked the witness the same exact question 6, 7, maybe 10 times, is to clarify. And if -- and if you're asking a different question, then perhaps she can answer it differently. I'm simply trying to move things along.

Is your question whether or not consumers, during the relevant period that

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you've now raised, actually --

MR. GOLDBERG: I want to ask my question. Don't ask my question.

MR. HONIK: I know. I'm not --

MR. GOLDBERG: No, stop. Ruben, stop. It's improper, and stop.

MR. HONIK: Here is what we're going to do.

MR. GOLDBERG: Stop it.

MR. HONIK: Here's what we're going to do. Here's what we're going to do.

MR. GOLDBERG: Tell me what we're going to do.

MR. HONIK: If you persist in asking the same question again, then we will have to stop. I think the witness has responded -- I think the witness has responded completely to your question. You seem not to understand --

MR. GOLDBERG: The objection is asked and answered. If that's your objection, say it.

MR. HONIK: Is there a pending question?

BY MR. GOLDBERG:

Q Dr. Conti -- Dr. Conti, there was an

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economic price that was paid for valsartan between 2012 and 2018, correct?
MR. HONIK: Object to form, asked and answered.
THE WITNESS: Okay. Again, let's start at the beginning. From my perspective, prospectively, there may be a demand curve for products that exist that cannot be met by a legitimate supply curve. In -- you can't get an economic price if there is not both a demand curve and a legitimate supply curve.
In this matter, I was asked to assume that these products at issue between 2012 and 2018 were adulterated and misbranded according to the Food and Drug Administration's definition.
By definition, if they were both adulterated and misbranded, there is no legitimate supply curve. And therefore, demand and supply cannot meet, and there cannot be an economic price.
BY MR. GOLDBERG:
Q But demand and supply did meet, and an economic price was paid for valsartan between 2012 and 2018, wasn't there?

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MR. HONIK: Object to the form, asked and answered.
Go ahead, Dr. Conti. You can explain it again.
THE WITNESS: Again, consumers and payors did not know that these products were adulterated and misbranded during the relevant time period. That's because, as I understand it, the manufacturers, who are the defendants in this case, were attesting that these products were meeting the evidentiary standard when they were not.
From my perspective in -- in analyzing this market, if I assume that these products are misbranded and adulterated, then there is no legitimate supply curve. And therefore, there is no meeting of demand and supply and no economic price.
BY MR. GOLDBERG:
Q There was a supply for these drugs between 2012 and 2018. You don't dispute that, do you?
MR. HONIK: Object to the form, asked and answered.
Go ahead.

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THE WITNESS: Again, I was asked to assume that that supply was adulterated and misbranded.
BY MR. GOLDBERG:
Q So the answer is, yes, there was a supply? Leaving aside your assumptions, you agree there was a supply of valsartan between 2012 and 2018?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: I think what you're asking is whether Diovan and Exforge, the brand -- the branded products, plus the generic drugs, were available to the U.S. market, were available --
THE COURT REPORTER: I'm sorry. You cut out, Doctor.
Were available to...
THE WITNESS: To be purchased in the U.S. supply chain between 2012 and 2018. If that is your question, then the answer is yes.
BY MR. GOLDBERG:
Q Okay. And between 2012 and 2018, valsartan -- that valsartan was purchased by consumers and third-party payors, right?

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A So consumers purchased Diovan and Exforge and it's generic equivalents during that time period. The at-issue drugs, I was asked to assume were adulterated and misbranded during that time period.
Q Do you have experience assessing the clinical value of drugs?
A As an economist? Yes. As a doctor, sadly, no.
Q Got you.
Have you conducted any clinical trials with respect to drug -- to drugs, pharmaceutical drugs?
A Have I conducted any clinical trials? I have been involved in clinical trials that have -- that are conducted --
THE COURT REPORTER: That are conducted...
THE WITNESS: On prescription drugs.
BY MR. GOLDBERG:
Q Have you reviewed the -- the -- strike that.
You understand that valsartan is -- an intended use of valsartan is to treat hypertension, right?

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A Yes. I mean, it is a member of a class of drug -- of a therapeutic class of drugs that are all intended to treat hypertension.
Q And another intended use of valsartan is to treat heart failure?
A I don't know that specifically.
Q Are you aware that, if left untreated, high blood pressure can lead to heart attacks?
MR. HONIK: Objection, outside the scope.
THE WITNESS: I mean, like, as an American citizen who's relatively well informed, yes, I understand that.
BY MR. GOLDBERG:
Q Okay. And -- yeah, I'm looking for your understanding as Dr. Conti, whether that's in your individual capacity as an expert. But you understand that high blood pressure, if left untreated, can lead to heart attacks, right?
A Yes. And I understand that there are many, many treatments to prevent heart attacks available.
Q And if left untreated, high blood pressure can lead to strokes?
MR. HONIK: Same objection, outside

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the scope of her report.
THE WITNESS: Thank you.
Again, I understand as, a general matter, that -- that high blood pressure is a risk factor for stroke and that high blood pressure can be treated in many different ways.
BY MR. GOLDBERG:
Q And if somebody has a heart attack, that can require hospitalization?
MR. HONIK: Same objection.
THE WITNESS: Yes. My mother had a heart attack, and she was hospitalized. I am generally aware of the facts.
BY MR. GOLDBERG:
Q And if somebody has a stroke, it can require hospitalization?
MR. HONIK: Same objection.
THE WITNESS: Yes. But again, there are many treatments -- I mean, we are so fortunate in the U.S. that there are so many treatments that prevent heart attack and strokes now from progressing to the point of requiring hospitalization or even, more tragically, death now. Deaths from strokes and heart attacks have dramatically come down over

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the past two decades with the advent of stents, but also the advent of many prescription drugs that support their prevention and treatment.
BY MR. GOLDBERG:
Q There would be medical expenses attributable to a heart attack for most consumers, right?
MR. HONIK: Same objection.
THE WITNESS: Are you saying as a general matter that -- that heart attacks entail costs?
BY MR. GOLDBERG:
Q Yes.
A Yes, definitively.
Q And the same -- the same is true for strokes?
A The primary prevention and treatment of strokes costs money.
COURT REPORTER: It what?
THE WITNESS: In the U.S.
COURT REPORTER: I'm sorry. The primary prevention...
THE WITNESS: And treatment of strokes in the U.S. costs money.
COURT REPORTER: Thank you.

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BY COURT REPORTER:
Q You'd agree that avoiding the complications from untreated hypertension could provide a value to a patient?
MR. HONIK: Objection, outside the scope.
THE WITNESS: As a general matter?
BY MR. GOLDBERG:
Q Yeah.
A I think a lot of Americans would view the primary prevention and treatment of underlying conditions to prevent strokes and heart attacks is of value. I mean, I certainly view that as valuable.
Q So if valsartan were treating someone's hypertension and that person, as a result, was avoiding a heart attack or a stroke because of their valsartan, that would be a value to that consumer?
MR. HONIK: Object to form.
THE WITNESS: That has therapeutic value. It doesn't have economic value from my reports on that.
BY MR. GOLDBERG:
Q So the consumer would get a

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therapeutic benefit from the treatment of valsartan -- their treatment with valsartan?
MR. HONIK: Object to the form, outside the scope.
THE WITNESS: Yeah. I think that's a good question.
So, again, from the perspective of my report, I was asked to assume that the valsartan products at issue were adulterated and misbranded, and therefore, they should not have entered into the U.S. class of trade.
Whether those products provided therapeutic value is -- is not of -- it's not -- it doesn't matter for the purposes of my calculation.
BY MR. GOLDBERG:
Q Well, do you dispute that those products provided therapeutic value?
MR. HONIK: Object to the form, asked and answered, outside the scope.
THE WITNESS: I don't know. I don't -- I don't have an opinion. You know, as an economist, I don't have an opinion.
BY MR. GOLDBERG:
Q Are you aware of any studies showing

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that between 2012 and 2018, valsartan was not effective in treating hypertension?
MR. HONIK: Object to the form, beyond the scope.
THE WITNESS: No. But it's -- again, has no moment, in my analysis, because again, I was asked to assume that those products at issue were misbranded and adulterated, and therefore would not have entered into the U.S. class of trade.
BY MR. GOLDBERG:
Q Are you aware of any warnings by the FDA between 2012 and 2018 that patients shouldn't take valsartan because it's not effective in treating hypertension?
MR. HONIK: Object to form, outside the scope.
THE WITNESS: So, again, it's of no moment -- moment in my analysis and my assignment in this case.
THE COURT REPORTER: What word are you using? Moment?
THE WITNESS: It's no moment.
MR. HONIK: It's of no moment, she said.

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COURT REPORTER: Of no moment. M-o-m-e-n-t? Moment.
THE WITNESS: Yes.
THE COURT REPORTER: Thank you. Thank you.
BY MR. GOLDBERG:
Q Is it your testimony that positive health outcomes have no economic value to consumers?
MR. HONIK: Object to the form, asked and answered, outside the scope.
THE WITNESS: That is not my testimony, sir.
BY MR. GOLDBERG:
Q Do you agree that positive health outcomes can have economic value to consumers?
MR. HONIK: Same objection.
THE WITNESS: That is not my testimony, sir.
BY MR. GOLDBERG:
Q Do you agree that positive outcomes, health outcomes, can have economic value to consumers, yes or no?
MR. HONIK: Same objection, asked and answered.
THE WITNESS: Of what, sir?

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BY MR. GOLDBERG:
Q Do you agree that controlled hypertension due to valsartan could have economic value to a consumer?
A Same objection.
THE WITNESS: I think I'm gonna -- I think I'm gonna ask just -- you to clarify.
So do you mean that prescription-based control of hypertension could have value to consumers?
BY MR. GOLDBERG:
Q Yes.
A There's my -- my -- my point is there's lots of -- I mean, my understanding is there's lots of ways that consumers can control their hypertension that go well beyond the availability of prescription valsartan.
Q But my question dealt with prescription valsartan.
A Okay.
Q Yes or no, if prescription valsartan were controlling a patient's hypertension, could that provide economic value to the patient?
MR. HONIK: Objection to form, asked and answered, outside the scope.

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THE WITNESS: What do you mean by "economic value"?
(Whereupon, there was a speaking interruption.)
THE WITNESS: I'm sorry --
THE COURT REPORTER: I'm sorry, who's speaking?
MR. HONIK: There was a question and objection and a partial answer from the witness. Did you get any of that?
THE COURT REPORTER: Yes.
MR. HONIK: Okay. Great.
THE WITNESS: And there was, like, something -- someone else started speaking.
MR. HONIK: And then someone interjected.
THE WITNESS: Correct. In the middle of my answer.
MR. HONIK: Okay. So other than Seth, everyone -- and myself, everyone should be muted.
BY MR. GOLDBERG:
Q Let me ask the question again.
Yes or no, prescription valsartan, when controlling a patient's hypertension, could

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that provide an economic value to the patient?
MR. HONIK: Object to form, asked and answered, beyond the scope.
You can answer.
THE WITNESS: Thank you. Seth -- Mr. Goldberg, what do you mean by "economic value" in that question?
BY MR. GOLDBERG:
Q Well, before you had said that that kind of control would provide a therapeutic benefit, not an economic value. And I'm just asking -- you used the phrase "economic value." What do you understand it to mean?
MR. HONIK: Object to the form.
THE WITNESS: Okay. Again, I -- we are talking about my definition of "economic value" in this specific matter based on assumptions that I was asked to make. You are using "economic value" in a way that is not consistent with how I just defined "economic value" for the purposes of my report. So in that --
BY MR. GOLDBERG:
Q Doctor --
THE WITNESS: Hold on.

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MR. HONIK: Don't interrupt her.
THE WITNESS: I'm going to ask again. I don't understand how you're using the term "economic value."
BY MR. GOLDBERG:
Q If a patient saved money on their health expenses because of their treatment with at-issue valsartan products, would that have provided economic value to the patient?
MR. HONIK: Is there a question?
MR. GOLDBERG: That is the question. Should I ask it again?
MR. HONIK: No, Jamie can read it, and we can all determine if it's a question. It sounded like a statement.
But, Jamie, can you read it back.
MR. GOLDBERG: I'm going to read -- I'm going to read the question.
BY MR. GOLDBERG:
Q If a patient saved money on their health expenses because of their treatment with at-issue valsartan products, would that have provided an economic value to the patient?
MR. HONIK: Object to form, beyond the scope, asked and answered.

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You can respond.
THE WITNESS: Thank you.
MR. HONIK: As best you can.
THE WITNESS: Thank you.
So for the -- I mean, as a general matter, if people are saving money, then there is some economic -- there might be economic value. That is not the way in which I am using the term "economic value" or "worth" or "worthlessness" in my report.
BY MR. GOLDBERG:
Q If a patient is -- strike that.
So if consumers received that economic value that you just described from their treatment of valsartan, is, in your view, the product still worthless?
MR. HONIK: Object to form, asked and answered, beyond the scope.
THE WITNESS: Okay. So from the Food and Drug Administration's perspective, there are two values associated with a drug -- associated with a prescription drug. One is related to the economic value. Is this product actually available to be sold into the U.S. market? Does supply meet demand?

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There is a separate value that is related to its therapeutic benefit. Only products that are considered to be legitimate products, they meet the evidentiary standard for sale in the U.S., could have therapeutic value, because you need to meet the evidentiary standard of being actually allowed on the market to be sold before you can have -- be judged to have additional therapeutic -- therapeutic value because it only -- the only way that you would know whether that product has benefit is if -- for a given patient, is if the product meets the evidentiary standard.

So in my analysis, that -- a product has value, economic value, if it meets the first part, that is there is a legitimate supply curve. Therapeutic value, whether that product is -- provides value or clinical value or maybe does have some economic value to a consumer is all predicated on it meeting --

COURT REPORTER: Is all predicated...

THE WITNESS: That goes above and beyond the economic value that I have been asked to consider.

I'm sorry. Is there a question? I'm

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hearing voices.

MR. HONIK: You're hearing background noise.

THE WITNESS: Okay. Okay.

BY MR. GOLDBERG:

Q Have you reviewed -- strike that.

You haven't reviewed any of the deposition testimony of any of the plaintiffs or class representatives in this case, correct?

MR. HONIK: Objection, asked and answered.

THE WITNESS: I think you asked that question to me this morning, and the answer -- my answer remains no.

BY MR. GOLDBERG:

Q Okay. So you're not aware of the plaintiffs and class representatives who have testified that they got therapeutic benefits from the at-issue valsartan they took? You're not aware of that testimony, right?

MR. HONIK: Object to the form, asked and answered, beyond the scope.

THE WITNESS: Again, it's of no moment for my assignment in this case. Therapeutic value associated with a product's benefits and

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potential downside costs are all predicated on the product being a legitimate product allowed for sale --

BY MR. GOLDBERG:

Q Of a product --

A Hold on, please, let me finish.

Allowed for sale in the U.S. market. I was asked to assume these -- these products were not legitimate products. They were not allowed into the U.S. market -- or they were not -- did not meet the evidentiary standard for sale. And therefore, that clinical value that they may have provided, is a separate matter.

Q That clinical value --

A Hold on. Hold on.

And not one that I evaluated. It's outside the scope of my report.

Q That clinical value is meaningless to you?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: Okay. Again, as, like, a human being, obviously, pharmaceutical products that are available for sale in the U.S. have -- may have clinical value to

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individual patients.

But for the purposes of my report, I'm using the term "economic value" in a very specific way, which is that the products meet the evidence -- either meet the evidentiary standard for being allowed to be sold into the U.S., or they don't.

I was asked to assume that they do not. And therefore, all the downstream potential benefits and costs associated with the products are of no moment -- excuse me -- are of no moment to me.

BY MR. GOLDBERG:

Q Let's look at it just from a human way, the human standpoint.

You agree that from a human standpoint, consumers who took valsartan between 2012 and 2018 may have had a therapeutic benefit from the drug, right?

MR. HONIK: Object to the form.

BY MR. GOLDBERG:

Q Human standpoint? Not -- not --

MR. HONIK: Object to the form.

THE WITNESS: I'm not a doctor, sir. I'm so sorry, Ruben.

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MR. HONIK: That's okay. I think Jamie got it.
THE COURT REPORTER: I have not heard anything clearly for the last 10 seconds.
MR. HONIK: Okay. Do you want to ask that question again?
MR. GOLDBERG: We can strike that question.
THE COURT REPORTER: I have --
MR. HONIK: It's stricken, Jamie.
COURT REPORTER: Can we go off the record for a second, please?
THE VIDEOGRAPHER: The time is 2:44. We're going off the record.
(Whereupon, a short break was taken.)
THE VIDEOGRAPHER: The time is 2:55. We're back on the record.
BY MR. GOLDBERG:
Q Dr. Conti, you'd agree that the therapeutic benefits that consumers may have gotten from valsartan between 2012 and 2018 would be different from one consumer to the next, right?
MR. HONIK: Object to form, outside the scope.
You can answer.

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THE WITNESS: Again, it's -- it's no moment to my report -- or to my opinions in this matter.
BY MR. GOLDBERG:
Q I -- I understand. I understand your view. But you've talked about the drug as being worthless, and we're talking about the therapeutic benefit of the drug and -- in the context of your opinion related to worthlessness.
My question is, you would agree that consumers would experience the therapeutic benefits from the at-issue valsartan products differently from consumer to consumer?
COURT REPORTER: Differently from consumers...
MR. GOLDBERG: Differently from consumer to consumer.
MR. HONIK: Object to form, asked and answered and beyond the scope of her report.
THE WITNESS: Okay. So I think that we are misunderstanding. I think you are misunderstanding the way in which I'm using the term "economic value" or "economic worth."
And so maybe if you would indulge me, I can just go back to my report. On page -- on

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Paragraph 42, I state, "Federal law establishes that non-safety and quality compliant adulterated and misbranded prescription drugs are not legitimate consumer products and cannot be lawfully or" -- "lawfully sold or distributed for sale."
It is in that context that I am discussing the economic worth or value of the at-issue products.
Whether or not an individual consumer, or there were consumers that may have --
COURT REPORTER: Let me just -- excuse me. Sorry. Let me just mute my microphone.
MR. HONIK: Go ahead. Go ahead.
THE WITNESS: Thank you. So the economic value that I -- let me just start from the beginning. Sorry, Jamie.
From my perspective, the economic value that is at issue in my report, in my opinions in this matter, are related to the product -- to the products being either meeting the evidentiary standard for sale or not.
Whether or not individual people -- there's a demand curve for these products, and individual people within that demand curve --

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or that make up that demand curve, experience therapeutic benefit or -- benefit or not, is of no moment to my opinion.
BY MR. GOLDBERG:
Q Is there -- is there some other economic value that you're excluding from your opinion that may have resulted from consumers taking the at-issue valsartan?
MR. HONIK: Object to the form.
THE WITNESS: I am using the term "economic value" in my report in the way in which I've justified, multiple times, and in the way that the judge in this case has defined "economic value" and its converse, "economic worthlessness."
BY MR. GOLDBERG:
Q How do you understand the judge in this case has defined "economic value"?
A I think it would be easier if I just read from my phone. I have his opinion in front of me. He says --
COURT REPORTER: Please just read slowly and clearly.
THE WITNESS: "This Court finds that contaminated drugs are economically worthless

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at the point of sale by virtue of the dangerousness caused by their contamination, regardless whether the sold VCDs actually achieve the medical purpose of lowering blood pressure." I can go on.

"Put differently, contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for.

"Further, contaminated drugs do create a present injury because their sale should never have occurred."

THE COURT REPORTER: Doctor, just for my clarification, what were you reading from?

THE WITNESS: I was reading from my cell phone.

BY MR. GOLDBERG:

Q And what were you -- what were you reading from?

A I was reading from an opinion of the court.

Q And who sent you that opinion?

MR. HONIK: Without waiving -- excuse me, without waiving the objection, I'll permit her to answer.

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THE WITNESS: So I have been aware of this opinion for a while, and the opinion was provided to me by counsel.

BY MR. GOLDBERG:

Q When was that?

A When did they -- when did I receive this via text on my phone?

Q Yes.

A Five minutes ago. But I have been aware of this before then.

Q So counsel texted you five minutes ago with the judge's opinion that you just read into the record?

MR. HONIK: Without waiving -- excuse me, without waiving the objection and privilege, I'll permit her to answer.

THE WITNESS: Yes. It was just texted to me. But again, I have been aware of this opinion for a while.

BY MR. GOLDBERG:

Q And which counsel texted that to you?

MR. HONIK: Without waiving the objection, I'll permit her to answer.

THE WITNESS: John Davis.

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BY MR. GOLDBERG:

Q And did John -- so we talked about the therapeutic benefits that may have -- that -- that consumers who took the at-issue valsartan products may have experienced. You don't dispute that consumers who took valsartan at-issue products may have experienced therapeutic benefits?

MR. HONIK: Object to the form, asked and answered, beyond the scope.

You may answer.

THE WITNESS: Again, the demand curve for these products may exist. From an economic theory perspective, the demand curve represents individual assessments of benefits and costs of prescription drugs. I am not disputing that there may have been a demand curve for these products. That is not my opinion.

My opinion is related to the supply curve. In other words, that products that do not meet the evidentiary standard are not allowed into the U.S. products of trade, they are not viewed as being legitimate products. From my perspective, those products are worthless.

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BY MR. GOLDBERG:

Q Yeah. And the consumers in that demand curve, as you have put it, those -- each consumer has -- has their own individual demand for the drug, right?

MR. HONIK: Object -- object to the form, asked and answered and beyond the scope.

You may answer.

THE WITNESS: Yes.

BY MR. GOLDBERG:

Q And --

A I mean, predicated, of course, on their doctor being willing to write a prescription and their insurer being willing to -- to insure that prescription, which is also predicated on FDA approval of the product.

But -- I mean, consumer demand does not live in a vacuum outside of physician prescribing behavior in this context.

Q And that physician prescribing behavior and the consumer demand for the at-issue valsartan products, that's individual from one consumer to the next. Why I need the drug is different from why someone else might need the drug, and so on, right?

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MR. HONIK: Object to the form, outside the scope, asked and answered, improper hypothetical.
You may answer.
THE WITNESS: I don't know what you mean by the term "need," sir.
BY MR. GOLDBERG:
Q Why I might be prescribed valsartan would likely be different than why someone else might be prescribed valsartan, and these are really individualized issues?
MR. HONIK: Same objection as previously stated.
THE WITNESS: I mean, that is not consistent with my understanding of demand for prescription drugs. I'm sorry.
BY MR. GOLDBERG:
Q Do you agree that therapeutic benefits that consumers who have taken at-issue valsartan may have been different from consumer to consumer?
MR. HONIK: Object to the form, asked and answered, beyond the scope.
THE WITNESS: Again, demand for prescription drugs is related, generally, to their benefits and their costs, predicated on

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the supply of those products being legitimate. In other words, the manufacturer actually meeting the evidentiary standard.
BY MR. GOLDBERG:
Q Yes or no -- yes or no, do you agree the therapeutic benefit --
A Sir --
Q I thought you were finished with your answer.
MR. HONIK: She's not.
THE WITNESS: I'm not. I'm not.
BY MR. GOLDBERG:
Q Why don't you go ahead and finish your answer, and then I'll ask my next question.
A Why don't ask you your question again because you interrupted me in mid-answer.
Q Oh, okay.
A Yeah.
Q Yes or no, do you agree that the therapeutic benefits that consumers who have taken -- let me -- let me rephrase.
Yes or no, do you agree -- yes or no, do you agree that the consumers who took at-issue valsartan would have received -- would have received different therapeutic benefits from consumer to

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consumer?
MR. HONIK: Objection, asked and answered, beyond the scope. I think you've asked her this four times already.
THE WITNESS: They may have received exactly the same therapeutic benefit.
BY MR. GOLDBERG:
Q And they may not, right?
A You're -- I'm sorry, sir, but this is impossible. You just interrupted me again, mid-answer, to the same question.
Q Go ahead.
A No. Please answer your -- please ask your question again, and then I'll answer it.
Q Yes or no, do you agree that the therapeutic benefits that consumers may have realized from taking the at-issue valsartan products would have differed from consumer to consumer?
MR. HONIK: Same objection.
THE WITNESS: Again, this is not a yes-or-no-type question. Consumers may have received exactly the same benefit from at-issue valsartan products, or they may have received different experiences of that product. It is of no moment in my opinions in this matter

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because, again, demand -- their demand is predicated on a legitimate supply curve. And I've been asked to assume that there was no legitimate supply curve.
BY MR. GOLDBERG:
Q You would agree, Dr. Conti, that we all have different risk tolerances for things we're willing to put into our bodies?
MR. HONIK: Same objection as previously, beyond the scope.
THE WITNESS: From the U.S. regulator's perspective, risk tolerance is of no moment. Again, only products that meet the evidentiary standard are allowed to enter into the prescription class of trade in the United States.
BY MR. GOLDBERG:
Q I'm asking you a different question. Answer my question.
You'd agree that people have different risk tolerances from what they're willing to put into their bodies from person to person?
MR. HONIK: Same objection as previously.
THE WITNESS: Okay. I'm going to

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answer your question again, which is, it is of no moment whether people want to consume illegitimate products. If there is no legitimate supply curve, those products cannot enter into the U.S. class of trade. That is -- that is the position of the U.S. government. And it's --

BY MR. GOLDBERG:

Q Is my answer, no, you --

A Hold on. Hold on.

Q You're still going?

A I am still going.

Q Okay. I mean, I would just say, Dr. Conti, I don't mean to be rude. But what happens is you -- you kind of -- the way you do this is you sort of get to the end of something. It seems like you're stopping, and then that's why I'm starting. I'm not trying to interrupt you. And then you --

A Mr. Goldberg, that is not the case. You just continue to talk over me. The mansplaining is a little bit challenging, frankly. But I'll try to do this again.

Q Okay.

A Again, Americans have a variation of

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their risk tolerance. That is of no moment for the legitimate class of trade for prescription drugs. If the product -- if pharmaceutical companies want to sell their products in the U.S., they must meet the evidentiary standard. Full stop.

Q You would agree that some consumers would be willing to accept a very low risk of a probable human carcinogen, whereas other consumers might not be willing to accept the risk of a probable human carcinogen?

MR. HONIK: Object to form, outside the scope.

THE WITNESS: It is of no moment in my opinions in this matter. The bottom line is that these manufacturers attested to that there was no contamination of these products by known human carcinogens.

BY MR. GOLDBERG:

Q Is the answer to my question, no, you don't agree?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: I have answered your question, sir, the best way that I know how.

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BY MR. GOLDBERG:

Q Your methodology does not take into consideration how consumers might have perceived the value of the at-issue valsartan to them, correct?

MR. HONIK: Object to the form.

THE WITNESS: My analysis presumes there is a demand curve for these products. What my analysis also presumes is that there is no legitimate supply curve for products that do not meet the evidentiary standard of the U.S.

BY MR. GOLDBERG:

Q What your analysis does not take into consideration is whether any consumer perceived that they received a therapeutic benefit that provided a value to them, right?

MR. HONIK: Object to the form, asked and answered.

You may answer.

THE WITNESS: Again, of course, it does. There is a demand curve for these products. That is not -- that is not the issue in this case. Of course, there's a demand curve, and I -- I describe it in my report. What my report is trying to explain is that there is no legitimate supply curve for

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products that do not meet the evidentiary standard of the U.S. government.

I was asked to assume that products -- that these products at issue between 2012 and 2018 did not meet the evidentiary standard. They were adulterated and misbranded. Therefore, there was no supply curve, in my analysis.

BY MR. GOLDBERG:

Q Are you familiar with what the FDA advised patients to do when the recalls were announced?

MR. HONIK: Object to the form, outside the scope.

THE WITNESS: Specifically, what do you mean?

BY MR. GOLDBERG:

Q Are you aware that the FDA advised people that they should not discontinue their use of valsartan until they spoke with their doctor about it?

MR. HONIK: Object to the form, asked and answered, outside the scope.

THE WITNESS: Again, my understanding is that there were multiple FDA communications

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when the contamination of these products and their adulteration became known. Is there a specific communication that you are referring to?
BY MR. GOLDBERG:
Q Well, I think my first question is -- and you can answer no if it's no.
Are you aware of the FDA telling patients they should not discontinue the use of their valsartan when the FDA announced the recalls?
MR. HONIK: Same objection as previously stated.
THE WITNESS: Okay. The FDA had multiple communications with consumers and other suppliers about these products. I'm asking you to be specific.
BY MR. GOLDBERG:
Q Do you want to turn to Tab 2 in your binder?
A Which binder?
Q Tab 2 is binder -- that would be binder, I guess, Volume 1 of 3?
THE COURT REPORTER: Will this be a new exhibit?
MR. GOLDBERG: Yeah -- we'll mark this

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as Conti 6. This is a --
(Whereupon, Exhibit Conti 6 was marked for Identification.)
BY MR. GOLDBERG:
Q Dr. Conti, I'm marking as exhibit Conti 6, a document entitled, "FDA Updates and Press Announcements on Angiotensin II Receptor Blocker Recalls." Do you see that?
MR. HONIK: Seth, what's Conti 5?
MR. GOLDBERG: Her expert report.
MR. HONIK: Thank you.
BY MR. GOLDBERG:
Q Are you familiar with this document, Dr. Conti?
A I am aware of this document.
Q This is a document that was cited in your report, right?
A There are many documents from the FDA documented -- sorry, cited in my report.
Q And this is one of those documents, right?
A I don't -- I don't recall.
Q If you turn to the very end of this document, it's the July 18th, 2018 statement.
A I don't see that, sir. I'm sorry.

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Q It's probably --
MR. GOLDBERG: For the tech -- it's almost three pages to the end. It's the last three pages-- three pages from the end.
THE WITNESS: Do you mean the one that says July 13th, 2018?
BY MR. GOLDBERG:
Q No, it's -- it's a page before it. It's the page before that.
A So that's three pages in. So four pages in, on July 18th, 2018, not the other --
Q Right.
A Okay.
Q Okay. And at the top of this page, it says -- where it says, "7-18-2018," do you see that?
A Yes.
Q And this page is referring to the recall of valsartan by ZHP. Do you see that?
A I don't see ZHP here.
Q Yeah. It's right in the second paragraph.
A You mean Zhejiang Huahai Pharmaceuticals?
Q Correct. Correct.
A Okay. So, yes, I see that here.

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Q Okay. And at the bottom of that page, there are two bullet points at the very bottom. Do you see those? And --
A Is that a question?
Q The first bullet point --
A Is that a question?
Q The first bullet point -- the first bullet point, the FDA is instructing patients taking at-issue valsartan that they should continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option. Did I read that correctly?
A I think you asked me two questions, but I see that you have read that -- that text correctly.
Q Did you consider at all in your assessment the FDA's instructing patients to continue -- to continue taking their medicine until they found an alternative?
MR. HONIK: Object to form, asked and answered, beyond the scope.
THE WITNESS: Again, from my perspective, there is a demand for these products. In my report, I was asked to assume that these products were contaminated,

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adulterated and misbranded. And therefore, there is no --
THE COURT REPORTER: I'm sorry. There is no...
THE WITNESS: There is no legitimate supply curve. The fact that the FDA reaffirms that there is a demand curve for these products and many other products that might treat someone's hypertension, is in my report. It is, by definition, considered.
My report is about the supply of these products.
BY MR. GOLDBERG:
Q The FDA is acknowledging that the at-issue valsartan may be providing a therapeutic benefit to the consumers who are taking it, right?
MR. HONIK: Object to the form, asked and answered, beyond the scope.
THE WITNESS: That's not what it says here on this -- on this document, sir.
MR. GOLDBERG: You can take down that document.
BY MR. GOLDBERG:
Q You're aware that there have been a number of recalls of valsartan since that one in

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July of 2018 that -- that went through July -- went through 2019, right?
A I am aware, as I stated earlier, that the FDA has had many communications with the manufacturers about these products and also the American public about these products over -- over time.
Q And in each of those recalls, the FDA made the same directive to consumers, that they should not discontinue their use of valsartan until they spoke with their doctor about an alternative?
MR. HONIK: Object to form.
BY MR. GOLDBERG:
Q Is it your testimony that the FDA saw no therapeutic benefit in the at-issue valsartan?
MR. HONIK: Object to form, asked and answered, beyond the scope.
THE WITNESS: So there were valsartan products that were not contaminated or adulterated or misbranded that were available during this time period, most notably by the manufacturer --
THE COURT REPORTER: I'm sorry. By the manufacturer...
THE WITNESS: By the manufacturer

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Novartis.
There were also many other treatments available for hypertension. I -- I haven't studied all of these FDA communications regarding all of the valsartan products, but my understanding is that the FDA has said to patients that they should discuss with their doctor continuing on the contaminated products and consider the use of non-contaminated or non-adulterated products for their treatment, which included valsartan, specifically the valsartan that were not contaminated or adulterated, but many other products as well.
BY MR. GOLDBERG:
Q And it also included the valsartan at issue, right, that the FDA was saying, don't discontinue your use of at-issue valsartan, to use your phrase "at-issue," until you talked with your doctor, right?
MR. HONIK: Object to the form, beyond the scope.
THE WITNESS: No. For example, in the document that we were just talking about, the FDA says -- the "FDA reminds consumers to continue taking your current medication until

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you -- until your doctor or pharmacist gives you a replacement or a different treatment option."
That is my understanding of what the FDA does, generally, when there are -- there are concerns about the quality of the product, and that is my understanding that that is what happened here.
BY MR. GOLDBERG:
Q And the products the FDA is referring to in that sentence are the at-issue valsartan products, right?
MR. HONIK: Object to form.
THE WITNESS: So, actually this -- the statement I just read, but on 7-24-2018, FDA publishes a list of valsartan-containing products not part of the recall. So it's actually talking about products that were not contaminated, adulterated or misbranded.
BY MR. GOLDBERG:
Q Why don't we go back to the statement we were talking about, which was July 18th, 2018? And that sentence appears --
A You told me -- you told me to put that away. I mean, just the one document, right?

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So like I said, to begin, when we started this long line of questioning, there were many, many communications the FDA had with American consumers and physicians and pharmacists about valsartan.

And so there are many products that are available to treat high blood pressure and hypertension in the U.S. market. We're very fortunate. And the FDA was telling consumers that they should talk to their doctor and talk to their pharmacist about their treatment in the use of both valsartan products, but also many other products that could control their condition as well.

Q The directive about the valsartan recall, by the FDA on July 18, 2018, to consumers about the valsartan recall, where the FDA says, "Continue taking your current medicine until your doctor or pharmacist gives you a replacement or a different treatment option," the FDA is saying if you are taking the at-issue valsartan products, you should continue taking those until you talk to your doctor, right?

MR. HONIK: Objection to form, asked and answered, beyond the scope.

You may answer.

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THE WITNESS: Thank you.

So, again, just going back to your specifically directed text, the FDA states, "Valsartan is used to treat high blood pressure and heart failure. Not all products containing valsartan" -- "valsartan are recalled, and this update will clarify which valsartan-containing products are being recalled."

It then goes on to say there are three current voluntary recalls, which involve Teva products, Prinston products and some other. And then they go on to say you should continue taking your current medication until you talk to your doctor about the treatment of your condition, where your doctor can give you a replacement or a different treatment option.

And then they go on to say, as you highlighted, "Not all valsartan-containing medications are affected and being recalled."

BY MR. GOLDBERG:

Q And the current medicine that they're referring to when they're saying "current medicine," could have been the at-issue valsartan products that somebody had in a bottle of pills at their house, right? And that the FDA is saying continue taking

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that until you speak with your doctor. Okay?

MR. HONIK: Object to form, beyond the scope, asked and answered.

You may answer.

THE WITNESS: Thank you.

So, again, there are many valsartan products, and there are valsartan products that don't contain contamination or adulteration. In fact, FDA says that in this specific wording on July 18, 2018.

What it's communicating is, to American consumers and their physicians and pharmacists, is that, for those of you taking valsartan products, go talk to your doctor about continuing taking those products or switching.

BY MR. GOLDBERG:

Q Yeah. Okay. And so if those products are some of the products that are at-issue now, you don't deny that the FDA was saying keep taking them?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: You mean the non-recalled products?

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BY MR. GOLDBERG:

Q No. I mean products that were recalled. But remember, somebody -- okay. On July 2018 -- on July 2018, if somebody had a bottle of valsartan that is part of the at-issue valsartan products that you're talking about, right? They're sitting at home. They've got their bottle of valsartan. It has NDMA in it. Okay? Just assume. Okay? Accept my assumption. It's hypothetical. Okay?

Somebody on July 2018, on July 28, 2018, has a bottle of valsartan, that is one of the at-issue products because it has NDMA in it, you would agree that the FDA is instructing that patient to continue to take that drug until they talk to their doctor, right?

MR. HONIK: Object to form, object to the hypothetical based upon facts not of evidence, asked and answered.

THE WITNESS: So, again, there are many communications the FDA had with American consumers, physicians and pharmacists about these products. In -- in this specific communication, the FDA reminds consumers, pharmacists and physicians, that there are

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valsartan products that are being recalled, and there are valsartan products that are not part of the recall. And it recommends to consumers that they -- they continue taking their product -- these products, and go talk to their doctor about it.

BY MR. GOLDBERG:

Q And that includes both valsartan that is being recalled and valsartan that may not be recalled, right?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: Yes.

BY MR. GOLDBERG:

Q Awesome.

And did you consider this FDA statement in forming your opinion?

A Again, I -- in my report, I assume that there is a demand curve for -- for these prescription drugs, including the at-issue products.

Q Yes or no, did you consider this specific statement in forming your opinion?

MR. HONIK: Objection, asked and answered.

THE WITNESS: Sir, I'm sorry. A

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demand curve, by definition, includes that consumers may -- pharmacists and physicians may want to continue using these at-issue products. The issue --

BY MR. GOLDBERG:

Q Is the answer to my question, yes?

MR. HONIK: You're interrupting her. You're interrupting the witness.

BY MR. GOLDBERG:

Q Is the answer to my question yes?

MR. HONIK: Objection, asked and answered. She's answered that question a dozen times already.

BY MR. GOLDBERG:

Q Did you consider this statement by the FDA in forming your opinion?

MR. HONIK: Objection, asked and answered.

THE WITNESS: Thank you.

Again, my opinion is that there was a demand curve for valsartan products that included the ones that were -- that are at-issue, that are contaminated or adulterated and misbranded, and others as well that were not.

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All this statement is saying is legitimating my presumption, which is there is a demand curve. And the FDA goes on, in later statements, to American consumers, saying there is a demand curve. All that's supporting my position.

MR. GOLDBERG: Why don't we take a two-minute break, if we can. Okay?

THE VIDEOGRAPHER: The time is 3:37. This ends Media Unit 3. We're going off the record.

(Whereupon, a short break was taken.)

THE VIDEOGRAPHER: The time is 4:02. This begins Media Unit Number 4. We're back on the record.

BY MR. GOLDBERG:

Q Dr. Conti, have you received any other text messages from plaintiffs' counsel today during the deposition?

MR. HONIK: Without waiver of the privilege it attaches to work product, I'll permit her to answer.

THE WITNESS: No.

BY MR. GOLDBERG:

Q And have any other documents been sent

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to you by email during the day from plaintiffs' counsel?

MR. HONIK: Same objection.

You may answer.

THE WITNESS: I'm a little afraid of my email, but I haven't checked. So I don't know.

BY MR. GOLDBERG:

Q Okay. You've -- you've talked about legitimate supply curve, and is -- is it your testimony that no -- that there is no price that could be paid where there's no legitimate supply?

MR. HONIK: Object to the form.

THE WITNESS: I don't understand your question, sir. I'm sorry.

BY MR. GOLDBERG:

Q Well, if -- thinking about your Figure 2 where there's no supply curve --

A Wait a minute. Wait a minute. Hold on. Just let me get my report, so I can reference what you're referring to.

Q So Figure 2 of your -- in your report shows "Demand with no Legitimatized Supply." That's -- that's how you've titled this figure, right?

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A That's accurate.
Q Is there -- is it -- is it your testimony that there's -- that no price could be paid under a scenario where there's, to use your term, "no legitimate" -- "no legitimate supply"?
A To be honest, it's a matter of economic theory. In order for there to be a price, there needs to be both demand and supply. What we've been talking about for the past, at least, hour, seems like more, is that in my model there is demand for these products, although demand falls off quite dramatically for these products when the recalls start.
But I have been asked to assume that the products at issue were adulterated and misbranded. Adulterated and misbranded products are not allowed in the U.S. supply chain, and therefore, there is no supply. And therefore, there is no meeting of demand and supply to arrive at a price.
Q So there is -- is it your testimony that there is no price that would -- could be paid for a product where there is no legitimate supply?
MR. HONIK: Object to the form, asked and answered.
THE WITNESS: As a matter of economic

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theory, price cannot be arrived at without there being both demand and supply. I have been asked to assume there is -- these products were adulterated and misbranded, and therefore, there is no supply that is legitimate for these products as -- as a matter of U.S. policy. And therefore, there can be no price.
BY MR. GOLDBERG:
Q Is -- is -- in your opinion, is price the same as value?
A So according to the FDA alone, there is both an economic price and a therapeutic -- well, an economic value and a therapeutic value. We've also talked about this quite a lot today.
There might be therapeutic value, in other words, that is encapsulated in the demand curve. People -- people trade off the benefits and costs of products. But there is no supply of illegitimate, adulterated and misbranded products in my -- in my model. And therefore, there is no price.
BY MR. GOLDBERG:
Q You said, "According to the FDA alone, there is both an economic price and a therapeutic value."

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A I meant economic value. And I corrected myself and said that there's a -- there's an economic value, and then there's a therapeutic value.
Q What -- is there something in particular that you're thinking about where the FDA has said there is an economic value to a drug?
MR. HONIK: Objection to the form.
THE WITNESS: Sure. I put it in my -- in my report. Let me get to the right paragraph, and I'll direct you to it.
Paragraph 26 of my report, "The FDA explains the rationale for its central focus on protecting consumers from adulterated and misbranded drugs on the web page as follows: At the turn of the 20th century, there were no federal regulations to protect the public from dangerous drugs. 'It was a menacing" -- "'menacing marketplace filled with products, such as William Radam's Microbe Killer and Benjamin Bye's'" --
COURT REPORTER: I'm sorry, Doctor. I just -- I lost you there a little bit.
Marketplace filled with products such as William...

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THE WITNESS: Sure. I'm sorry.
"'It was a menacing market'" -- so, "'It was a menacing marketplace filled with products such as William Radam's Microbe Killer and Benjamin Bye's Soothing Balmy Oils to cure cancer,' said John Swann, Ph.D., a historian at the Food and Drug Administration. Products like these were, at minimum, remedies that picked the pocket of the user." That's what I mean by "economic value."
"But they could also be downright harmful." That's what I mean by "therapeutically harmful."
"I emphasize the text" -- "the text in italics because the FDA's statement underscores the harms from adulterated and misbranded products as twofold: First, economic losses from purchasing products that are adulterated and misbranded and second, the possibility of clinical harm from consumption of adulterated and misbranded products."
From my perspective, there are two types of value, and therefore, two types of usefulness or worthlessness. There is the economic value, and then there is a therapeutic

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value. The economic value, products such as these -- and products that are adulterated and misbranded should never have entered into the U.S. class of trades. That is the position of the U.S. government, that we do not allow products such as these onto the U.S. market.

BY MR. GOLDBERG:

Q I -- I thought you said that it was the FDA's view that -- that there was no -- that this term "economic value," you had said, "the FDA alone." And then in your last answer, you referred to you having two views of value, economic value and therapeutic value.

Are you basing -- are you basing your view of economic value on what the FDA says?

MR. HONIK: Object to the form. You may answer.

THE WITNESS: My view is both a matter of economic theory; there is demand that does not meet supply, and therefore there is no price. But also, it is predicated, as my understanding of FDA regulation, and also, frankly, regulation that the pharmaceutical industry itself has -- has wanted, which is that there is only the legitimate supply of

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products that are not adulterated and misbranded into the U.S. market, those that are valuable.

BY MR. GOLDBERG:

Q Let's talk about the first part --

A Wait. Wait. Wait. Wait. Wait. Hold on. Let me just -- let me just finish.

So it is the -- it is the position of the pharmaceutical industry in the United States since at least the '60s, that they have wanted there to be very clear guidance about what is a legitimate product, that meets the evidentiary standards, and what is a not legitimate product that does not.

It is their position that they do not want products on the market that are misbranded, adulterated or otherwise contaminated.

Q Are you finished?

A I am. Thank you for asking.

Q So the first part of that question, you said -- or answer, you said, "My view is more the matter of economic theory. There is demand that does not meet supply, and therefore, there is no price." And then you went on to talk about the FDA's view?

A Yes.

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Q Just in terms of the FDA --

A And -- wait, and -- just so that you're not mischaracterizing me.

It's also the pharmaceutical industry's view that they want to be known as producing and entering products into the U.S. and selling products into the U.S. that are legitimate, that do meet the evidentiary standard as distinguished from products that do not.

Q Just as you don't want me to interrupt you, I'd appreciate it if you don't interrupt me.

A I was just trying to clarify your mischaracterization of my position.

Q In your answer, going back, you refer to the economic theory of supply and demand. What economic treatises have you been relying on for the theory that where there's no legitimate supply, there -- there's no possibility for a delivery of price?

A That's Economics 101.

MR. HONIK: Objection, asked and answered.

THE WITNESS: It's Economics 101.

MR. HONIK: I think you got your answer, Seth.

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THE WITNESS: Thank you.

It is Economics 101. Literally, my high school student was just taught that price is a function of supply and demand. So that is -- that is a familiar concept to anyone who has taken elementary economics.

BY MR. GOLDBERG:

Q What economic theory are you relying on for the point that where there is a cGMP violation in a drug, there is no legitimate supply? Which economic theory are you relying on?

MR. HONIK: Objection, mischaracterizes her previous response.

THE WITNESS: Okay. Again, Economics 101. There can be a demand curve for products that have no supply, legitimate supply. If there is no legitimate supply, there is no economic price. That -- that is just -- that is just elementary economics.

BY MR. GOLDBERG:

Q I'm asking you, what is the economic theory for an adulterated drug equals no legitimate supply? What's the economic theory for that?

A Sure.

So this is the most highly -- one of

the most highly regulated consumer products in the -- in the U.S. marketplace. And it is the U.S. regulator's perspective that products that do not meet the evidentiary standard of cGMP are not considered prescription drugs.

And I can point you to the orange book where the FDA makes that statement. In other words, in order for a prescription drug to be sold in the U.S., to enter into the commercial class of trade and be sold in a pharmacy, it must be produced in accordance with the cGMP at minimum and attested to by the manufacturer, and in addition, meet other evidentiary standards for safety and efficacy.

That is the position of the U.S. government.

Q Would you agree that patients who would not have taken the at-issue valsartan would have -- because it was not supplied, in your view of the world, would not -- would have needed to take another medication to treat their hypertension?

MR. HONIK: Objection, beyond the scope.

THE WITNESS: So are you saying that -- because I think I'm -- I think what you're asking is, would there be demand for

treatment of hypertension and high blood pressure regardless of whether these products were on the market? Is that what you're asking?

BY MR. GOLDBERG:

Q Sure.

A Okay. Consumers in America who suffer from high blood pressure or hypertension or other related conditions certainly seek treatment. They demand treatment for those conditions.

My understanding, and as I understand it, your own experts have suggested that there were many treatments available for those conditions, including uncontaminated, unadulterated valsartan manufactured by Novartis, among others. And other -- many other products and non-pharmaceutical products --

THE COURT REPORTER: I'm sorry, Doctor, can you repeat the end of that?

THE WITNESS: Sure.

Where -- so my understanding is that there are many products that are pharmaceutical, in addition to other non-pharmaceutical products, that can treat the underlying conditions to either mitigate the

hyper -- high blood pressure or hypertension or prevent sequella.

THE COURT REPORTER: Thank you.

BY MR. GOLDBERG:

Q Would there have been a cost associated with having to take one of those alternative medications or treatments?

MR. HONIK: Object to the form, beyond the scope.

THE WITNESS: It depends.

BY MR. GOLDBERG:

Q If someone had to take a different ARB, they might have had to pay for that ARB, right?

MR. HONIK: Object to the form.

THE WITNESS: They may have. They may have decided to manage their -- their treatment in many other ways. Physicians can choose to do many things. We know that demand for valsartan products that were recalled dropped precipitously, and so those consumers went elsewhere. Where they went, there are many, many options available to them and their physicians.

BY MR. GOLDBERG:

Q Is it -- your analysis doesn't take

into account the cost that a consumer might have had to pay for a different medication?

MR. HONIK: Object to the form.

THE WITNESS: Or do you mean or other management techniques? Because there are many management techniques.

BY MR. GOLDBERG:

Q Sure.

A Some which would have cost less.

Q Your -- your analysis doesn't take into account any other -- any -- the cost of any alternative treatment of medication, right?

MR. HONIK: Object to the form.

THE WITNESS: That is outside the scope of my report, sir.

BY MR. GOLDBERG:

Q Is it possible that if it weren't -- if they hadn't taken the at-issue valsartan products, consumers might have paid more for a hypertension medication?

MR. HONIK: Object to the form.

THE WITNESS: I've learned in this world anything is possible. I mean, there are many, many ways of controlling high blood pressure and -- and other related conditions

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that people may have taken valsartan for during this time period. I have no opinion whether or not those other therapeutic alternatives, including doing nothing, were lostless or costly.

BY MR. GOLDBERG:

Q Why is the cost of an alternative medication not pertinent to your analysis?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: Because my damages calculation is focused on the injury that occurred to consumers and to end-party payors for contaminated, adulterated and misbranded valsartan products that were recalled during the time period. Whether or not people went elsewhere, the downstream economic costs to that -- to that contamination are of no moment in my economic calculation.

And maybe the way that I like to think of it is this way, which is I was asked to calculate damages associated with this injury, the defendants selling adulterated, misbranded products into the U.S. marketplace that consumers --

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THE COURT REPORTER: That consumers...

THE WITNESS: And end-payors or insurers didn't know about.

Injury occurs -- in other words, if you get hit by a car, injury occurs at the time of the car, being hit. If people go elsewhere after they hit their -- after their car was hit, maybe they buy a new car or it's more costly, maybe they go without a car all together, that's -- that's not related to my calculation. It's of no moment. The economic --

BY MR. GOLDBERG:

Q You --

A Hold on. The economic loss occurs at the time of injury.

Q You said that this drug should not have been sold to those consumers, right?

A That's not what I said, sir.

Q So the drug could have been sold to consumers?

MR. HONIK: Object to form.

THE WITNESS: That's not what I said either, sir.

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BY MR. GOLDBERG:

Q Okay. You said the drug shouldn't be sold, and that it was an illegitimate supply, right?

MR. HONIK: Object to form.

THE WITNESS: They are not the same thing, sir.

BY MR. GOLDBERG:

Q Okay. If consumers would have paid more for a different drug because valsartan -- because the at-issue valsartan were not sold, doesn't -- wouldn't that have mattered to your analysis?

MR. HONIK: Object to the form, asked and answered, improper hypothetical, facts not in evidence.

You can answer.

THE WITNESS: Thank you.

You have asked this question four times, and I have already answered it. But I'm happy to answer it again.

Again, injury occurs at the time of the accident, at the time of -- at the time of the accident. Whether consumers would have gone on to buy something else after the injury occurred is of no moment. There was an

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economic loss. People bought things that shouldn't -- they -- that under the assumptions that were given to me, Counsel, should not have entered into the legitimate class of trade.

BY MR. GOLDBERG:

Q Okay. So I just asked you, your testimony is that these drugs should not have entered into the class of trade, right?

A No. What I was asked --

Q And my question is --

A No. What I was asked to assume is that these products were adulterated and misbranded. If a product is adulterated and misbranded, according to U.S. regulation and pharmaceutical manufacturers, they are not allowed to enter into the U.S. class of trade. And therefore, there was no supply.

Q Okay.

A Injury occurs because these products -- these contaminated products entered into the U.S. class of trade and people bought them. And insurers purchased -- insurers paid for them. The economic loss arising, therefore, from the purchase of products that, under this theory of damages, should not have occurred.

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What people would have done after the injury, they switched products to another prescription drug, they managed their hypertension by diet and exercise, they underwent stent therapy, all of those other things are of no moment to my assessment of economic loss.
BY MR. GOLDBERG:
Q I'm not talking about after the injury at this point. I'm talking about instead of the injury. Instead of buying the at-issue valsartan because it was not on the market and a consumer bought a different ARB or a different drug and paid more for that, that doesn't matter to your -- would have paid more for that, that doesn't matter to your analysis?
MR. HONIK: Objection, asked and answered, improper hypothetical.
THE WITNESS: So -- I mean, really the alternative here is not -- is that the manufacturers actually sold unadulterated, properly branded product, not that consumers were forced to go elsewhere, in my economic analysis.
BY MR. GOLDBERG:
Q In an economic analysis where a

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consumer would have taken a different drug instead of the at-issue valsartan, and they would have paid the same or more for that different drug, did the consumer have an economic injury?
MR. HONIK: Objection, asked and answered, improper hypothetical.
THE WITNESS: From my perspective, if the consumer did not buy adulterated or -- and misbranded, illegitimate valsartan products, they are not injured.
So all of those people between 2012 and 2018 that took Novartis-brand valsartan that was not recalled or contaminated, they are out of my class. They are out of the -- my calculation of damages.
All of those people between 2012 and 2018 that used other therapeutic modalities to treat their hypertension are of no moment to me, in my economic analysis.
My economic analysis is only focused on the people who purchased adulterated and misbranded valsartan products that were ultimately recalled.
BY MR. GOLDBERG:
Q And if they didn't make that purchase,

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they would have had to purchase some other drug, right?
MR. HONIK: Object to the form. It's been asked and answered, I don't know, 15 times already.
THE WITNESS: There are many, many treatments for hypertension and high blood pressure out there. Some of them are pharmaceutical. Some of them are other things. It's immaterial to my perspective. I am simply focused on the people who actually bought or insured the contaminated, misbranded and adulterated products at-issue in this matter.
BY MR. GOLDBERG:
Q Do you know the difference between compensatory damages and punitive damages?
MR. HONIK: Object to the form, outside the scope, calls for an expert legal opinion.
THE WITNESS: No. I'm not a lawyer. Maybe in my future life.
BY MR. GOLDBERG:
Q In your view, the damages you calculated, are you -- are you calculating damages to compensate consumers or their loss or deter

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manufacturers from making drugs that have adulterations or misbranding?
MR. HONIK: Same objection to the extent it calls for a legal conclusion.
You may answer.
THE WITNESS: I'm sorry. I -- I didn't quite follow. Can you slow down and ask not a compound question, but in parts?
BY MR. GOLDBERG:
Q Turn to Paragraph 45 of your report.
A So we're moving on? You're not going to ask that question?
Q I'm moving on.
A Oh, okay.
Q Do you have Paragraph 45 up?
A Uh-huh.
Q In Paragraph 45, you write, "Assigning a non-zero value to non-safety and quality compliant products is perverse. To do so would be to incentivize and legitimize cheating and noncompliance by manufacturers and other members of the United States pharmaceutical supply chain."
Did I read that correctly?
A That's what it says.
Q Is it your opinion that -- that the

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damages you calculated are intended to disincentivize manufacturers from cheating and noncompliance?
MR. HONIK: Object to the form.
BY MR. GOLDBERG:
Q Well, let me put it another way.
Are you -- are you suggesting that manufacturers should be deterred from cheating and noncompliance?
A It is the U.S. government's position, evolving over time, and also pharmaceutical manufacturers' position, that the illegitimate, misbranded, adulterated, contaminated, criminal class of trade of prescription drugs should be minimized at, if at all, at all possibilities.
There's 100 years of focus on reducing products that pick the pocket of consumers, don't do what they say or could even cause harm. To allow those products onto the market to legitimate this type of cheating, goes against U.S. policy and, frankly, the pharmaceutical industry's position, for the better part of many decades.
BY MR. GOLDBERG:
Q So in calculating the damages the way you have, are you taking into account the need to

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deter manufacturers from wrongdoing, as you put it?
MR. HONIK: Object to the form, calls for a legal conclusion, beyond the scope of her report.
THE WITNESS: I'm sorry. I don't quite understand your question. Can you please repeat it?
BY MR. GOLDBERG:
Q In calculating -- in calculating the damages that you've calculated, are you trying to also account for some punishment, if you will, of manufacturers -- of the defendants for manufacturing drugs that had an impurity in it?
MR. HONIK: Same objection. She's not a lawyer, beyond the scope.
THE WITNESS: I'm sorry. I don't -- I don't quite understand what you mean. Am I trying to punish the manufacturers? Is that what you're asking?
BY MR. GOLDBERG:
Q Yes.
MR. HONIK: Same objection.
THE WITNESS: Again, that's no moment to my -- that has no moment in my opinions in this matter. I was asked to calculate economic

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damages associated with misconduct.
BY MR. GOLDBERG:
Q Right. So --
A Myself -- I mean, from, again, an economic perspective, these products are worthless. The court has agreed. Consumers and third-party payors suffered an economic harm. And my analysis calculates that economic harm, which is the full price of the product that they paid at the pharmacy counter.
Q Why do you -- why is it necessary for you to -- to say that a nonzero value is perverse and would incentivize to you? What -- what does that have to do with your economic calculation?
A It goes -- because it goes -- because assigning a nonzero value goes against U.S. policy and the pharmaceutical companies' own position on the matter of illegitimate products for the better part of 50 -- and if you count from 1906, the better part of more than 100 years of U.S. policy. But, again, products that are illegitimate, that do not meet cGMP, that would not be allowed to come into the U.S. market, they have no economic value. And the court agrees with me.
THE COURT REPORTER: And the -- I'm

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sorry.
THE WITNESS: And the court agrees with me on that point.
COURT REPORTER: Thank you.
THE WITNESS: Thank you.
BY MR. GOLDBERG:
Q I just want to confirm, you have not made any attempt to consider whether a consumer would have paid a different co-payment for a different drug but for their purchase of valsartan?
MR. HONIK: Object to the form.
THE WITNESS: I already answered this question, sir.
But, again, all I considered in my analysis is what consumers actually paid for these at-issue products.
BY MR. GOLDBERG:
Q And the same is true for TPPs? All you considered for end-payors or third-party payors is what they actually paid for the product?
THE COURT REPORTER: Is what they actually...
MR. GOLDBERG: Paid for the product.
THE WITNESS: Correct.

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BY MR. GOLDBERG:
Q Just moving on into another area of your report --
THE WITNESS: Excuse me. If we're moving on, before there's a question pending, do you mind if we take a break, please?
MR. GOLDBERG: No, that's fine.
THE VIDEOGRAPHER: The time is 4:41. We're going off the record.
(Whereupon, a short break was taken.)
THE VIDEOGRAPHER: The time is 4:52. This begins Media Unit Number 5. We're back on the record.
BY MR. GOLDBERG:
Q Dr. Conti, can you turn in your report to Paragraph 58?
A I'm there.
Q At the beginning of this paragraph, you say, "Plaintiffs' counsel have asked me to calculate damages for four different theories of liability against the manufacturer defendants and two different theories of liability and one theory of unjust enrichment against the defendant retailers."
Do you see that?

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A Yes.
Q The unjust enrichment damages that you calculated, did you apply the same measure of damages to all of the different theories of liability?
A They differ by the states included in the calculations.
Q To your knowledge, is that the only difference that -- as between these different theories of liability?
A Generally, yes. And then -- I mean, in terms of the defendants, the terms of the retailers, there's both data and --
THE COURT REPORTER: And what? And what, Doctor?
THE WITNESS: And states that are different from the retailers.
BY MR. GOLDBERG:
Q In terms of the measure of damages for all of the liability, leaving aside unjust enrichment, the measure of damages for all of them is the same, which is a full refund of the price paid at the point of sale?
MR. HONIK: Object to the form.
THE WITNESS: Correct. Yeah, correct.

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Again, the retailers are different. But --
THE COURT REPORTER: But from the defendants...
MR. HONIK: I think she said the retailers are different.
THE WITNESS: Right. For the defendants, the measure of economic liability is the same. It's the price that was paid. And for the retailers, it's different.
THE COURT REPORTER: Thank you.
BY MR. GOLDBERG:
Q And leaving aside unjust enrichment, in what way is -- is it different for the retailers?
A Let's go down and talk about it.
So the -- the retailers sold the product to consumers, and they obtained their own benefit from selling these products. So it's the economic loss or economic gain associated with the retailers' sale that's different than the defendants' sale.
Q Okay. I'm not going to get into the economic damages for the retailers, at this point. I'm -- I'm going to leave that for somebody else.
You have that -- you made that statement. I just wanted to clarify that one point.

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In terms of the -- the manufacturer damages, you -- you relied -- you're relying on data from IQVIA? Am I correct?
A Right. I'm relying on national sales by product, manufacturer, month, state and payment types of who the payor is. And I'm also relying on national data related to the co-payment amounts, or co-insurance amounts, that consumers paid. Again, by product, payor, state, month, year.
Q And how did you get the data that you relied upon?
A I instructed my staff to purchase the data on my behalf.
THE COURT REPORTER: To purchase?
THE WITNESS: To purchase, yes.
BY MR. GOLDBERG:
Q Did you provide a specific instruction as to what -- what parameters you were looking for for them to purchase?
A I think I just made that clear in my previous answer, sir.
I -- I look at IQVIA data every day in my research, and they are known as the gold standard for pharmaceutical sales of legitimate prescription drugs in the U.S. consumer market.

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Q Do you know whether there are any limitations to the IQVIA data you relied upon or purchased?
A Oh, goodness, Mr. Goldberg, there are always limitations, but they are the gold standard. They are used by the pharmaceutical industry themselves for assessing sales of products both in their own market but also in competitor markets. And, you know, I am not aware of a product that is better.
Q Do you know that there are some sources of data that IQVIA is not able to obtain and makes projections in place of the data that they can't obtain?
A So the Xponent data that I used is comprised of approximately 92 percent of total prescription sales for legitimate consumer product -- legitimate pharmaceutical products in the U.S. class of trade. There are some holes in their audit, but with prescription manufacturers and pharmacies. But those are not holes that are particularly relevant to these specific products.
What I mean by that is that we know that Xponent data does not have -- does not have good purview into drugs that are sold to some

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hospitals in the U.S. and some specialty pharmacies.
But those are not -- these are not -- these products at-issue here are not really those drugs. It's largely drugs that are -- that are used in the inpatient setting to treat very, very sick people in the ICU and -- and otherwise.
The retail class of trade from regular pharmacies like CVS and Walgreens are the -- are the products that are at-issue here and that -- in that class of trade.
THE COURT REPORTER: That class of -- that class of trade...
THE WITNESS: That is at-issue in this math certificate.
Xponent also doesn't capture all co-insurance and co-payment amounts. It captures approximately 80 percent that are purchased, not all that are purchased or all that are paid in the legitimate consumer -- legitimate pharmaceutical market in the U.S. And my methods account for that.
BY MR. GOLDBERG:
Q How do your methods account for that? How do you explain that?
A So I explain the limitations of this

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data in -- in my report. I've also written -- I've used Xponent data for my own research in many, many different contexts. And so those limitations for this type of data are very well known. They're well characterized, and I cite those in my report, the fact that Xponent doesn't contain all consumer co-insurance.
THE COURT REPORTER: Co-insurance...
THE WITNESS: Co-payment amounts that consumers pay -- paid for these products is accounted for in a specific way in this analysis. Specifically, I took average insurance and co-payment amounts by product, month, year, manufacturer and applied that to the analysis --
THE COURT REPORTER: The analysis...
THE WITNESS: When appropriate.
THE COURT REPORTER: One more time.
THE WITNESS: When appropriate.
COURT REPORTER: I'm sorry. Thank you.
THE WITNESS: No problem. It's the end of a day.
BY MR. GOLDBERG:
Q From the IQVIA data, the Xponent data,

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you -- that data does not identify the specific patients who purchased valsartan, right?
A It's inclusive of all patients that purchased valsartan or who prescribed and dispensed valsartan by definition.
Q You can't use that data to identify any particular patient, right?
A Correct, it is inclusive of all.
Q And you can't use that data to identify any particular payor for valsartan?
A That is -- that is incorrect.
Q I thought - I thought I just heard you say that, so maybe I misheard you.
A No.
MR. HONIK: Wait. Wait. Wait for a question. Wait for a question.
MR. GOLDBERG: Okay. I did mishear you. You said prescribe and dispense.
BY MR. GOLDBERG:
Q Does the IQVIA -- does the IQVIA data permit you to determine a particular class member's damages in this case?
A The IQVIA data allows me to disaggregate sales of products by product, and by payor type.

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Q So no, you couldn't get to a particular class member's data in this case through the IQVIA data?
A I'm not sure I understand what you mean by "class member." I mean, my -- my -- excuse me. My understanding is that class members are, by definition, defined buy payor type and also by state.
Q Did you look at the IQVIA data and determine what a particular consumer paid for valsartan in cash?
MR. HONIK: Objection, asked and answered.
THE WITNESS: It is inclusive of all payments made by all consumers who are presumable class members, and it's inclusive of all payors that are inclusive of all payor class members by month, state, year and product.
BY MR. GOLDBERG:
Q Right. It doesn't get -- it doesn't allow you to drill down to what a particular consumer paid --
MR. HONIK: Do you mean without more? Do you mean without more? Is that what you

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mean, Seth?
MR. GOLDBERG: The question is pending. I asked her about the Xponent data.
MR. HONIK: The problem is you've asked it six times. I think she's answered it as best she can. It's aggregate data is what she's saying, and if you're asking --
MR. GOLDBERG: Are you testifying?
MR. HONIK: No. I'm just -- I think you're going round and round.
But answer it as best you can.
THE WITNESS: Can you restate the question, please?
BY MR. GOLDBERG:
Q The IQVIA data doesn't allow you to drill down to what a particular class member paid for at-issue valsartan?
MR. HONIK: Object to form, asked and answered.
THE WITNESS: So, again, IQVIA's data is specific to the product, month, year, payor and state. And therefore -- and across all the U.S. And therefore, it is -- it is -- it contains in it every single potential class member, whether they be a consumer or a

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specific payor. There are payor variables that are pretty specific in the IQVIA data that would allow me to characterize or identify payors to a pretty specific degree.
BY MR. GOLDBERG:
Q What -- what is that specific degree?
A So I know where the payor is located, what the payor's type is, and also what the payor's name is for each individual product, month, year, combination.
Q And by "payor," you're -- when you're talking about -- you're talking about third-party payors? When you're talking about getting to that level of specificity, you're talking about third-party payors or consumers?
A Third-party payors.
Q When you calculated average co-pays, did you exclude co-pays -- 0-dollar co-pays in your averaging?
MR. HONIK: Object to form.
THE WITNESS: I did not.
BY MR. GOLDBERG:
Q Is it the -- you just mentioned the -- the specificity with respect to TPPs. Is it your view and understanding that all TPPs are advised in

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the IQVIA data?
A Well, the TPPs that I used for my damage calculations met certain criteria.
Q What were those criteria?
A They're listed in my report.
Q Do you want to point to that?
A Sure, give me a second. Are you with me?
Q Uh-huh.
A Okay, great. Page 29 of my report, Paragraph 75, I define end-payor class damages. And in Paragraph 75, I say, "...my calculation of End-Payor Class damages includes three parts. First, I limit both sets of Xponent data" -- both the total national sales but also co-insurance co-payments, they are actually two separate datasets, "to exclude cash paid claims as well as claims paid by the following state and federal government entities (based on plan categories or plan names in the Xponent data):"
"CHIP," Children's Health Insurance Program, "federal assistance programs, Medicare Parts A and B...", Medicare Part A is for hospital plans, we were just talking about that before. We're not talking about that class of trade here.

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And Medicare Part B, which is the insurance that covers drugs that are infused or injected or otherwise given to patients in a medical office.

State insurance programs -- assistance programs, to include ADAP. ADAPs are state assistance programs with people with HIV or other infectious disease. Tricare, a military program -- a military insurance program, department of Veterans Affairs, another -- another military insurance program, the Indian Health Service, state employee plans, which include city and county plans -- sorry. Not -- I didn't exclude city and county plans. And Workers Compensation plans.

And you can see there's a note that follows that. This occurs for 464 distinct combinations of manufacturer, product, state and month out of the 36,000ish -- oh, no, I'm sorry. Right. It includes the valsartan class definitions and exclusions. It's -- it's Footnote 17.

Q Why -- why did you -- what do you understand your reason for excluding the claims paid by those state and federal government entities? Why did you want to exclude those from your calculations?

A That was a --

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THE COURT REPORTER: That was a what?

THE WITNESS: A part of the instruction of counsel.

BY MR. GOLDBERG:

Q Do you understand that you're -- you're excluding them to avoid including claims in your calculation by payors who are excluded from the GPP class definition, such as --

THE COURT REPORTER: Such as -- sorry. Hold on. I didn't hear the end of the question.

MR. HONIK: She needs you to repeat it, Seth, the last part, the last part. Jamie, read what you have.

MR. GOLDBERG: Such as government payors.

MR. HONIK: Object to form and object to the extent it calls for a legal conclusion or expertise.

You can answer.

THE WITNESS: Thank you.

Again, the exclusion was based on instruction from counsel.

BY MR. GOLDBERG:

Q Do you have any view as to whether

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government payors should be included in your damages calculation?

MR. HONIK: Same objection as previously stated.

THE WITNESS: It's by instruction of counsel.

BY MR. GOLDBERG:

Q Whatever counsel told you to calculate, that's what you calculated?

MR. HONIK: Objection to form.

THE WITNESS: That is not what I said, sir.

BY MR. GOLDBERG:

Q Whatever counsel told you to include is what you included, and what they told you to exclude is what you tried to exclude.

MR. HONIK: Object to form. That is not her testimony.

THE WITNESS: That is not my testimony, sir.

BY MR. GOLDBERG:

Q Going down into this paragraph, you say, "I did not exclude Medicare Part D plan sponsors because they are private entities that offer prescription drug benefits, and I did not

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exclude federal employee plans because they are provided by private insurers."

A There's other things in that sentence as well that you kind of skipped over.

Q Again, just focusing on the first part of the sentence, Medicare -- the Medicare Part D plan, part of that --

A Do you mean the second part of the sentence? Do you mean the second?

Q No.

A I mean, I'm just trying to follow, sir.

So the first part of the sentence, which you kind of skipped over half of it, I said, "I also excluded prescriptions for which the consumer is not covered by insurance but uses a coupon that reduces their total costs, including discount cards and vouchers. I did not exclude Medicare Part D plan sponsors because they are private entities that offer prescription drug benefits, and I did not exclude federal employee plans because they are provided by private insurers."

Q I want to focus on the Medicare Part D plan part of that. Okay?

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In that part of this paragraph, you're referring to third-party payors who are private insurers that have, as part of their product mix, a Medicare Part D plan; am I correct?

A I don't quite understand your question. I'm sorry.

Q Your sentence says, "I did not exclude Medicare part D plan sponsors because they are private entities that offer prescription drug benefits."

My question is, you're referring to third-party payors who have Medicare Part D plans, private entities that have Medicare Part D plans as part of their -- their offerings to consumers, correct?

A No.

MR. HONIK: Object to form.

BY MR. GOLDBERG:

Q What are you referring to then?

A So there are third-party payors, so, for example, Aetna. Aetna includes sales plans that are to consumers that are -- for people who are employed, for people who are in the individual insurance market, and also sells plans to consumers who may be Medicare eligible.

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A Medicare Part D plan is one that is sold by commercial insurers such as Aetna, United, et cetera, to seniors who are required to have Part D prescription drug benefits.

Q Are you familiar with how Medicare Part D claims are reimbursed?

A I am. But how is that relevant to this case, sir?

Q Do you believe that the TPPs that provide Medicare Part D plans bear 100 percent of the cost of reimbursement for enrollees of those plans?

MR. HONIK: Object to the form.

THE WITNESS: I think -- okay. So what insurance -- what defines a commercial insurance plan is that consumers, you and me, my mother, who is Medicare eligible, pay premiums to a commercial insurer, as opposed to paying premiums or are otherwise insured by a private -- by a public insurer.

Part D plans receive premiums from the people who are insured by them, just like the plans that are sold to non-seniors receive premiums from the people who are insured by them. They're exactly the same.

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BY MR. GOLDBERG:

Q Do you know whether those Part D plan sponsors that are commercial entities receive funding from the federal government?

MR. HONIK: Object to form.

THE WITNESS: They do under certain circumstances, but that's separate from the premiums that are paid by actual seniors for their insurance coverage.

BY MR. GOLDBERG:

Q Did you factor into your calculation any amounts that the federal government might have paid to private commercial third-party payors that offer Medicare Part D plans?

MR. HONIK: Object to form, asked and answered.

THE WITNESS: Again, consumers who are seniors are required to have -- to purchase prescription drug benefit from these Part D plans. They pay premiums. And then they have an insurance schedule on how much they are required to pay out-of-pocket for each and every prescription drug that is dispensed to them.

Since injury occurs at the point of

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sale, it is the insurance price that is paid, both by the payor itself, and by the consumer at the pharmacy counter, than it is at issue in my damage calculation.

Whether or not there are side payments or subsidies or anything else that those plans or those consumers may face, is of no moment to my economic analysis.

And the way I like to think about it is that if I am injured in a car accident, if I receive side payments from my mother, for example, to pay for my car repair or pay for myself to the -- receive medical treatment, that has nothing to do with the economic loss I suffered from having -- from being injured, from being in a car accident. And therefore, those side payments, even if they exist, are of no moment in my analysis. Injury occurs at the point of sale.

COURT REPORTER: I'm sorry?

THE WITNESS: Injury occurs at the point of sale.

BY MR. GOLDBERG:

Q So did you not factor in that third-party payors who offer Medicare Part D plans

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receive respective subsidies from the federal government to cover their beneficiaries' prescription drug purchases?

MR. HONIK: Object to form, asked and answered.

THE WITNESS: Again, they only do so sometimes in a prospective way. Largely, those payments are made retrospectively and only for certain types of prescription drugs. I have not seen any evidence to suggest that the valsartan products at issue in this case were ones that were either directly paid by the federal government or were part of those retrospective payments that the government might have made.

Usually, those type of direct payments, or retrospective payments, are made for really expensive specialty drugs used in the cancer setting, in the immunology setting, with prices of $10,000 or more for treatment. That's not what we're talking about in this case.

BY MR. GOLDBERG:

Q But you haven't considered any amount that the federal government might have paid to any

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TPPs for -- in connection with their Medicare Part D plans, right?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: Again, I'm not aware of any evidence to suggest that third-party payors receive direct payments from the federal government to underwrite any senior's sale or purchase of valsartan at-issue products in this case.

Again, usually those type of payments in the catastrophic limit, for example, of Part D, those are pages that are made either retrospectively after the injury would have occurred, or are for products that are not at issue here. They're for drugs that are really expensive and for which patients have blown through the donut hole, are in the catastrophic phase of their benefit design. That's -- that's not what we're talking about here.

These are generic products that are -- I think, you know, the average co-insurance amount that I -- that I calculated was somewhere on the order of $12. Consumers could, I think -- to get out of the -- into the

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donut hole, they would have to spend something like $400, maybe a little bit more, in order to even get into that phase of the benefit.

And I think the limit for catastrophic coverage during this time period is more like $8,000.

COURT REPORTER: Is what?

THE WITNESS: Is more like $8,000.

BY MR. GOLDBERG:

Q Yes or no --

A It's not a yes or no question, sir.

Q This -- let me ask the question.

Yes or no, did you factor in any payments made by the federal government to third-party payors offering Medicare Part D plans? Yes or no, did you factor that into your calculation?

MR. HONIK: Object to form, asked and answered. You can't direct the witness to answer it in a manner in which you'd like. If she tells you she's unable to answer it yes or no, she can provide an answer.

Please do so.

THE WITNESS: Thank you.

So, again, the vast majority of

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seniors who have prescription drug benefits through Part D -- my mother is one of them. I might know more about this than I should. They pay premiums, and they also pay at the pharmacy counter when they get a prescription at a low-cost generic, such as the at-issue valsartan in this case.

So that -- whether -- if those TPPs, those third-party payors receive side payments from the federal government, or other types of payments from the federal government, is really not material to this because there's no evidence to suggest that low-cost generics are ever in that phase of the benefit where the third-party payor would actually pay the side payments.

BY MR. GOLDBERG:

Q What do you understand the third-party payors' point of sale to be? You mentioned the consumer paying at the retail pharmacy. What do you understand the TPPs' point of sale to be?

A When the consumer goes to fill their prescription at the pharmacy counter, the pharmacy runs a check on what insurance that patient has and how much the patient needs to pay out of pocket.

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The point of sale for both, what the pharmacy expects to receive from the consumer and what the pharmacy expects to receive from the insurer is exactly the same.

Those transactions occur within seconds, and the pharmacy dispenses the product to a consumer predicated on their existence of insurance and the insurance saying that, yes, they will pay for that product, dispense that beneficiary. It's exactly the same.

Q We were -- you talked a lot about value and therapeutic value of the at-issue valsartan, what the consumers receive. And you explained that there was an illegitimate supply for at-issue valsartan, and therefore, even though there was a demand, the drug was worthless. Is that the same -- that worthless as to consumers, is that the same as to third-party payors?

MR. HONIK: Object to the form. It's a little bit --

THE COURT REPORTER: I'm sorry. I didn't hear the end of the question.

MR. HONIK: Sorry. You trailed off, Seth. Just cover the --

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BY MR. GOLDBERG:

Q Is your view that there was an illegitimate supply of valsartan as to consumers the same for TPPs?

MR. HONIK: Object to form.

THE WITNESS: I don't think that's the question you asked me, sir.

BY MR. GOLDBERG:

Q Well, I'm asking you that question.

A Okay. Can you go back and ask that question again because I was focused on trying to get clarity on the previous question that you asked.

Q Is your view that there was an illegitimate supply of at-issue valsartan as to consumers the same for TPPs?

A I was asked to assume that there is no legitimate supply of adulterated and misbranded prescription drugs for the at-issue valsartan products between 2012 and 2018 in order to calculate damages in this matter. For both consumers and end-party payors that are -- that are included in the class.

As we have already discussed, my assessment assumes there's a demand curve. What my assessment does not do is assume that there is a

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legitimate supply curve based on the assumptions given to me by counsel.

Q And regardless of any benefit that a TPP might have received, they got from their insured's treatment with the at-issue valsartan, your view is that the drug, as to that TPP, is still worthless?

MR. HONIK: Object to form, asked and answered.

THE WITNESS: I'm sorry. I didn't -- really did not follow your question. There's a lot of compound phrases there. Can you please restate?

BY MR. GOLDBERG:

Q Regardless of any benefit that a TPP might have perceived they received from their insured's treatment with the at-issue valsartan, as to that TPP, the drug is still worthless in your view?

MR. HONIK: Object to the form, asked and answered.

THE WITNESS: I don't understand what you mean by a third-party payor receiving value or benefit. Can you please define?

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BY MR. GOLDBERG:

Q Does a third-party payor receive a value when its insureds are effectively treated with a drug?

MR. HONIK: Object to the form. They're not consuming -- they're not consuming drugs. I think -- I think that's the problem, Seth.

THE WITNESS: I don't follow.

MR. HONIK: You're kind of mixing apples and oranges, I think.

THE WITNESS: There is no therapeutic value to the third-party payor.

BY MR. GOLDBERG:

Q Does a third-party payor --

A I don't even understand that, that context.

Q Does a third-party payor receive an economic value when its insureds are effectively treated with at-issue valsartan?

MR. HONIK: Object to the form of the question.

THE WITNESS: That's a lot -- again, that's a lot of compound statements and assumptions that you're making.

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BY MR. GOLDBERG:
Q Well, let's just --
A Again, third-party payors are not consumers, so they don't receive any therapeutic benefit from their beneficiaries consuming a product. And they certainly don't receive any -- any benefit from consumers consuming a product that was adulterated and misbranded and may have actually caused clinical harm.
Q Do you have any evidence that there was any clinical harm in this case from 2012 to 2018?
MR. HONIK: Object to the form, outside the scope.
THE WITNESS: I don't think that's the issue. Again, that's why -- that's why I don't understand at all. I mean --
BY MR. GOLDBERG:
Q Just --
A Okay. I'm sorry, Mr. Goldberg. You've interrupted me over and over again today. There is a word for that, it's mansplaining. Please let me finish.
So, again, I don't understand the idea that third-party payors could benefit from consumers

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taking adulterated prescription drugs. That should not -- that, I was asked to assume, should not have entered into the U.S. class of trade. That is -- that is your assumption of your -- underlying your hypothetical question.
THE COURT REPORTER: Seth, when you get to a good point, can we take five minutes, please?
MR. GOLDBERG: Yes, this is a good time.
MR. HONIK: Okay. Let's take five, and then we will reassess --
THE VIDEOGRAPHER: The time is 5:37. This ends Media Unit Number 5. We're going off the record.
(Whereupon, a short break was taken.)
THE VIDEOGRAPHER: The time is 5:50. This begins Media Unit Number 6. We're back on the record.
BY MR. GOLDBERG:
Q So in your report, you talk about the different levels of the pharmaceutical supply chain?
A Where are you referring, Mr. Goldberg?
Q I'm going to get you there. It starts at Page 19 and goes through to Page 22.

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And in Paragraph 52, you describe third-party payors.
A Is that a question?
Q Are you aware -- are you familiar with the different contractual arrangements that third-party payors have in terms of sourcing and paying for and being reimbursed for at-issue valsartan?
A I think I'm -- that was a compound question, right?
So what do you mean by third-party payors being paid for?
Q Okay. Are you -- are you familiar with the contractual arrangements that third-party payors have, say, with pharmacy benefit managers?
A Pharmacy benefit managers are a member of the supply chain of prescription drugs in the United States. And some payors have their own PBM, so there is no contractual relationship. They all have a PBM, and some third-party payors contract with PBMs to provide fund services to their beneficiaries.
Q These are differences from third-party payor to third-party payor, right?
A I really don't understand that

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question. I'm sorry.
Q Each third-party payor has its own set of contractual arrangements that control its distribution and -- and insurance of at-issue valsartan?
MR. HONIK: Object to form.
THE WITNESS: That is not my testimony. Like I just said, the biggest payors in the U.S. are their own PBM. They own their own PBM, so there is no contractual relationship. They are the PBM. There are some payors that contract for external PBM services, and there's some third-party payors that directly go with pharmacies to dispense drugs to their beneficiaries.
BY MR. GOLDBERG:
Q Are there other -- are there other arrangements that you can think of that third-party payors have?
A Not -- I mean, that -- those are general buckets that characterize third-party payment for prescription drugs sold in the pharmacy setting.
Q Do third-party payors pay pharmacies directly, to your understanding?

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A They can and do or dispense prescription drugs every day.
Q Are you aware of any contractual arrangements a third-party payor was not able to keep and satisfy as a result of the sale of at-issue valsartan?
MR. HONIK: Object to form, outside the scope.
THE WITNESS: I don't understand your question at all. I'm sorry, what does "keep" mean here?
BY MR. GOLDBERG:
Q Are you aware of any -- any arrangement a third-party payor has that it's not able to satisfy as a result of at-issue valsartan?
MR. HONIK: Same objection.
THE WITNESS: I don't know what you're referring to. I'm sorry. I don't follow.
BY MR. GOLDBERG:
Q Are you aware of whether any third-party payor did not -- ended up reaching a contract with a pharmacy benefits manager because of their covering at-issue valsartan?
MR. HONIK: Same objection.
And to the extent it calls for a legal

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conclusion, you may answer if you understand.
THE WITNESS: I don't understand the question. I'm sorry. Like I said before, there are a variety of different types of arrangements. Many third-party payors -- many insurers pay pharmacies directly for dispensed drugs. Some third-party payors may contract with pharmacy benefit managers for the coverage of some drugs.
I think what you're referring to is the latter category, but I really -- I don't understand your question. I don't know what you mean by "keep a contract" in this setting.
BY MR. GOLDBERG:
Q Does it matter to your analysis that different -- there were different levels of NDMA or NDEA in the manufacturer defendants' valsartan?
MR. HONIK: Object to the form. Facts not in evidence.
You may answer.
THE WITNESS: Thank you.
So my understanding is, during the at-issue time period, between January 2012 and 2018, the manufacturers attested to the Food and Drug Administration that there were no

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known contaminants of nitrosamines in these products.
BY MR. GOLDBERG:
Q Does it matter to your analysis that the specifications for valsartan during that time period did not require -- or did not include nitrosamines?
MR. HONIK: Object to the form, hypothetical, inappropriate, facts not in evidence.
You can answer.
THE WITNESS: Again, the manufacturers themselves attested on their drug forms to the Food and Drug Administration that there was no contamination.
BY MR. GOLDBERG:
Q My question is, does it matter to your analysis that there -- that nitrosamines were not included in the specifications for valsartan from 2012 to July 2018?
MR. HONIK: Object to the form, improper hypothetical. Those are not dispensed.
You may answer.
THE WITNESS: Again, my understanding

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is that the manufacturers of the at-issue valsartan products attested to the Food and Drug Administration over and over again that these products were manufactured to be compliant, at minimum, with cGMP. And they also attested to the fact that there were no contamination of nitrosamines in these at-issue valsartan.
MR. GOLDBERG: I see we're at 6 o'clock?
MR. HONIK: Yeah. Why don't we go off the record, video and steno?
THE VIDEOGRAPHER: The time is 6 o'clock. We're going off the record.
(Whereupon, the deposition concluded at 6 o'clock p.m.)

CERTIFICATE

I, Jamie I. Moskowitz, a Shorthand (Stenotype) Reporter and Notary Public, do hereby certify that the foregoing Deposition, of the witness, RENA M. CONTI, Ph.D., taken at the time and place aforesaid, is a true and correct transcription of my shorthand notes.

I further certify that I am neither counsel for nor related to any party to said action, nor in any way interested in the result or outcome thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this 16th day of February, 2022.

Jamie Ilyse Moskowitz

Jamie Ilyse Moskowitz
License No. XI01658

Ruben Honik, Esq.
ruben@honiklaw.com

February 16, 2022.

RE: In Re: Valsartan, Losartan, et al.
2/10/22, Rena Conti, PH.D. (#5064909)

The above-referenced transcript is available for review.

Within the applicable timeframe, the witness should read the testimony to verify its accuracy. If there are any changes, the witness should note those with the reason, on the attached Errata Sheet.

The witness should sign the Acknowledgment of Deponent and Errata and return to the deposing attorney. Copies should be sent to all counsel, and to Veritext at cs-ny@veritext.com

Return completed errata within 30 days from receipt of testimony.

If the witness fails to do so within the time allotted, the transcript may be used as if signed.

Yours,
Veritext Legal Solutions

In Re: Valsartan, Losartan, Et Al
Rena Conti, PH.D (#5064909)

ERRATA SHEET

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_____ _____
Rena Conti, PH.D Date

In Re: Valsartan, Losartan, et al.
Rena Conti, PH.D (#5064909)

ACKNOWLEDGEMENT OF DEPONENT

I, Rena Conti, PH.D, do hereby declare that I have read the foregoing transcript, I have made any corrections, additions, or changes I deemed necessary as noted above to be appended hereto, and that the same is a true, correct and complete transcript of the testimony given by me.

_____ _____
Rena Conti, PH.D Date
*If notary is required

SUBSCRIBED AND SWORN TO BEFORE ME THIS
_____ DAY OF _____, 20___.

_____
NOTARY PUBLIC

f

[reviewed - see]

Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY. THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

Veritext Legal Solutions complies with all federal and State regulations with respect to the provision of court reporting services, and maintains its neutrality and independence regardless of relationship or the financial outcome of any litigation. Veritext requires adherence to the foregoing professional and ethical standards from all of its subcontractors in their independent contractor agreements.

Inquiries about Veritext Legal Solutions' confidentiality and security policies and practices should be directed to Veritext's Client Services Associates indicated on the cover of this document or at www.veritext.com.

EXHIBIT 8

Data Disclosure Policy:
Legal Proceedings and Government Investigations

Introduction. IQVIA market research offerings are highly valuable and proprietary resources, built over decades of careful design, significant capital investments, and the expertise of many thousands of employees. To retain the value of these offerings, the licenses IQVIA grants to its clients generally allow only internal use of IQVIA market research data. However, IQVIA acknowledges and understands that clients may have a need for limited external disclosure of some IQVIA Data.

One of these circumstances relates to disclosures of IQVIA Data in Legal Proceedings and Government Investigations. This Data Disclosure Policy is intended to advise IQVIA clients and IQVIA personnel of the conditions under which IQVIA may grant consent for the limited disclosure of IQVIA Data in Legal Proceedings and Government Investigations.

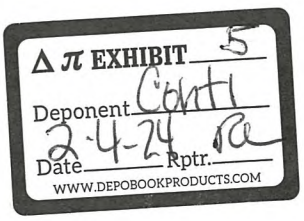
Definitions.

- *IQVIA Data*. Any syndicated IQVIA data licensed by IQVIA to a client, including information derived from that IQVIA data. IQVIA Data includes information from national market research audits; subnational information services; reference data relating to healthcare professionals, healthcare organizations, medicines or other healthcare related products; and real world data (e.g., data from electronic medical records, longitudinal prescription data, claims data).

- *Legal Proceeding*. Any lawsuit, hearing, or other proceeding between two or more adverse parties heard and determined by a court, tribunal or other judicial, arbitration, mediation or government authority, including any filings made in connection with such proceeding.

- *Government Investigation*. Any government investigation or inquiry involving requests for IQVIA Data (e.g., through a subpoena, investigative demand, summons, etc.). If such proceeding has been filed in a court or other tribunal, it is considered a Legal Proceeding.

- *Protective Order*. A court ordered document that protects and limits the disclosure of confidential and proprietary information in Legal Proceedings. A sufficient Protective Order restricts disclosure of the IQVIA Data only to a limited group of individuals or entities that reasonably needs access to such information, extends confidentiality protections to third party information that is produced by a party to the Legal Proceeding,



and allows recipients of the IQVIA Data to use such information only for the purposes of the Legal Proceeding.

- *Confidentiality Mechanism*: A document, agreement, statute or other mechanism that protects and limits disclosure of confidential and proprietary IQVIA Data in Legal Proceedings or Government Investigations.

Scope. Clients who are in possession of IQVIA Data, current and/or historical, may have a need to disclose confidential and proprietary IQVIA Data in Legal Proceedings or Government Investigations. Client licenses of IQVIA Data permit only internal use. Accordingly, any external or other disclosure of IQVIA Data requires IQVIA's prior written consent.

➢ Disclosure of IQVIA Data in Legal Proceedings and Government Investigations requires an IQVIA consent letter to be executed by the client or its legal representative agreeing to certain terms and conditions protecting IQVIA Data in the proceedings (discussed below).

➢ To the extent the client would like to disclose IQVIA Data to a retained expert or consultant solely for internal analysis, and no Protective Order or other Confidentiality Mechanism exists, the client may seek a Third Party Access (TPA) Limited License Agreement ("TPA License") from IQVIA. The IQVIA client must submit the request using the TPA Program portal. Any disclosure or use beyond the internal analysis in any Legal or Government Proceeding is not permitted under the TPA and requires written consent from IQVIA pursuant to this policy.

➢ To the extent the client's request falls outside the scope of the above, please reach out to your client representative and the IQVIA Global Legal Department.

Terms and Conditions for Obtaining IQVIA Consent.

➢ Consent for the disclosure of IQVIA Data in Legal Proceedings and Government Investigations may only be granted where IQVIA has determined that its confidential and proprietary information will be sufficiently protected from unnecessary and unlimited disclosure.

  - In Legal Proceedings in the United States, consent for the disclosure of IQVIA Data will be permitted pursuant to a fully executed Protective Order.
  - In other jurisdictions and in Government Investigations, consent for the disclosure of IQVIA Data will only be permitted under a sufficient Confidentiality Mechanism.

- Some offerings may have additional approval requirements, such as any data offering that utilizes prescriber-level data.

➢ In addition, consent may only be granted where a client or its legal representative agrees to certain other terms and conditions necessary to protect IQVIA's proprietary and confidential interests, including but not limited to:

- The IQVIA Data will only be used for purposes directly related to the Legal Proceeding or Government Investigation.
- The IQVIA Data will be marked at the highest level of confidentiality available under the Protective Order or Confidentiality Mechanism.
- The client will notify and cooperate with IQVIA in maintaining the confidentiality of the IQVIA Data and protecting the IQVIA Data from any public disclosure.
- The client acknowledges that IQVIA is not agreeing to (1) serve as an expert on behalf of any party; (2) prepare or offer any testimony, affidavits, declarations or other evidence regarding the interpretation of the IQVIA Data or the services performed by IQVIA; (3) provide any advice or engage in any advocacy with respect to witness testimony or expert analysis of any party; or (4) provide any opinion as to the relative merits of any party's position in the Legal Proceeding or Government Investigation.
- The IQVIA Data used by a client representative in preparing exhibits or other documents to be introduced in a Legal Proceeding or Government Investigation will be extracted and presented accurately and correctly sourced (i.e. correct universes and measures are used for the claim required and that the data is used in accordance with applicable laws and in the country/ies where they are permitted to be used), will not be used in a misleading way, and shall not be represented as a report, document, or exhibit prepared or endorsed by IQVIA.
- IQVIA will be held harmless from any claims or costs arising from or relating to the use of the IQVIA Data in connection with the Legal Proceeding or Government Investigation.

Important Disclosure. While clients may often be required to produce IQVIA Data in Legal Proceedings and Government Investigations, it should be advised that IQVIA Data may reflect projections, estimates, and forecasts that are the result of a combination of confidential and proprietary technologies, statistical methodologies and a significant number of sources. These estimates reflect the independent judgment, expertise and opinion of IQVIA representatives to arrive at a reasonable approximation of market activity. The IQVIA Data is intended to support sales, marketing and research applications, and it is highly reliable for those purposes. The IQVIA Data, although appropriate for its intended purpose of supporting business and marketing analyses in industries such as the pharmaceutical industry, contains data that is susceptible to error or variance, and is not intended to be used as direct evidence or to establish any fact.

Accordingly, IQVIA offers no assurances that the IQVIA Data will be suitable for use as evidence in any Legal Proceeding or Government Investigation. For more information regarding this topic, please see the latest IQVIA Information Services Published Specifications.

What is Not Covered by This Policy. This Policy does not cover purchases of IQVIA Data for use in Legal Proceedings or Government Investigations, or any other types of disclosures of IQVIA Data. Please contact your account representative for such purchases.

Changes to This Policy. IQVIA reserves the right to modify this Policy at any time.

EXHIBIT 10

IQVIA Information Services
Published Specifications

(January 2018)

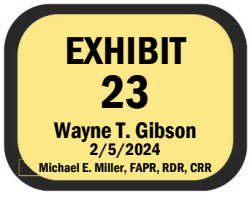
Introduction

IQVIA is a leading provider of information and technology services for the healthcare industry, covering markets in 100+ countries around the world. A leader for more than 60 years, we blend industry expertise and advanced technology to deliver in-depth analytics on healthcare dynamics. We have one of the largest and most comprehensive collections of healthcare information in the world, spanning sales, prescription and promotional data, medical claims, electronic medical records and social media. We continuously innovate to keep pace with a global healthcare environment that is highly dynamic and increasingly complex and interdependent.

IQVIA information services represent a wide array of offerings reporting on various aspects of medicines and health care in countries around the world. In market research and other methods of estimating activity in the world, numbers are prepared using judgment and skill, not simply arithmetic. Further, information is initially input at the source by thousands of people, often manually, in thousands of organizations. Further still, this information is often gathered from IT systems that were designed for and serve a purpose other than measuring market activity (e.g., electronic medical records, pharmacy systems, payment systems), so the design of the data fields and the choices available to populate those fields are not intended to meet the needs of IQVIA's clients. Each of these characteristics of the underlying components of market measures has an impact on the ultimate accuracy and meaning of the final numbers.

Although there is an inclination to view numerical data as fact, IQVIA information represents an estimate of measured activity and should be treated accordingly. To use it effectively, it is important to have a sufficient understanding of how the information is sourced, processed, standardized, produced and reported. Further, proper practice involves the use of IQVIA information in combination with other information (e.g., knowledge based on skills and experience, other information and observations in the marketplace) to make decisions. To help customers obtain the most value from IQVIA information services and use the information in a manner that is consistent with its specifications, this document provides an overview of the processes employed by IQVIA to produce and report these estimates, and a list of appropriate practices in the use of such information.

We prepared this document to help you use IQVIA information services more effectively. This document provides an overview of methods we employ to source, collect, cleanse, bridge, edit and organize information. We then apply some combination of sophisticated computer processing, statistical projections, advanced analytics, forecasting methodologies and our skills and experience to provide you with answers, insights and tools. We don't use every method described in this document in every one of our hundreds of offerings; we use commercially reasonable efforts to employ many of these in each of our offerings commensurate with the nature and cost of the service in order to provide our customers with the most comprehensive and effective measures of pharmaceutical and health care markets in the world.



IQVIA Processes

Data Sourcing

IQVIA collects information from a wide variety of sources. Some of that information is collected through surveys, which may be completed by respondents as the activity occurs or completed later based on review of records or an individual's recollection, and which may be completed by the person engaged in the activity (e.g., provider) or someone else at their location (e.g., nurse, technician, administrative staff). Other information may be gathered from business records based upon fields of information that an organization is willing to provide, with the information gathered as a by-product of the business process which produces it (i.e., health records and payment systems are designed for a particular purpose, so data collection for other purposes is a secondary use of the information). Although IQVIA seeks accurate, complete and timely information from these sources, the information is frequently provided with limited assurances regarding quality and timeliness. In addition, IQVIA frequently uses pre-defined formats for responses, financial incentives, feedback reports, notification requirements for changes in data or systems, retention of back-up copies of data at the source, record layouts, contractual undertakings to avoid the blocking of data at the request of others and other approaches to encourage the delivery of high quality and timely data provided by these sources, commensurate with the nature of the data collection activity (e.g., approaches appropriate for a physician completing a monthly market research survey versus a large commercial organization providing gigabytes of transactional information on a daily basis).

Data Receipt

IQVIA takes care to establish reasonable methods of delivery for information from hundreds of thousands of sources to support the timely and secure delivery of data to IQVIA. Following receipt of data from its sources, IQVIA employs a variety of initial quality control checks and processes to ensure data has been properly delivered to IQVIA. IQVIA also contacts sources if data is not received on a timely, complete or accurate basis as a result of these initial quality control checks (to the extent detectable). Data record statistics (e.g., record counts) accompany data delivery to ensure data shipment records match data receipt records. Further, IQVIA maintains various metrics and parameters regarding the characteristics of each individual data file received and promptly investigates discrepancies or unusual variances identified through its automated quality control processes. Data suppliers are frequently contacted to assist with resolution of these issues. IQVIA promptly performs manual adjustments to data based on acknowledgement by supplier of file issues, allowing for prompt correction of many issues prior to the start of database creation and the report production schedule. IQVIA maintains readily available back-up copies of incoming data sets in conjunction with report production in the event data processing issues are identified, providing IQVIA with the ability to rapidly re-process data.

Data Editing / Validation

In addition to the processes referenced above, IQVIA has invested significantly in the development of proprietary data cleansing, editing, and other sophisticated tools to find data issues and provide visibility to any issues as they become apparent. The benefit for IQVIA clients is our ability to proactively identify situations that may exceed standard variances. Although these quality control checks and processes will vary by data type, examples include: (a) examination of the information in various fields for each transaction to ensure the field contains a valid value, (b) maintenance of various metrics and established variances regarding the characteristics of each transaction (e.g., days' supply of product, quantity by product), (c) maintenance of various metrics and established

variances regarding the characteristics of the source, (d) analysis of historical distribution, prescribing, dispensing or other applicable patterns of measured activity, and (e) analysis of historical reporting patterns. If unusual variances are encountered, IQVIA investigates the situation or takes other appropriate actions, often working closely with the sources of the data to determine if the variances are acceptable or require corrections. Data exceeding acceptable variance ranges will not be utilized unless verified. Despite all these processes and procedures to capture data quality errors upon receipt, it is impossible to capture all errors that might exist within the boundaries of the acceptable variance levels and therefore can be a source of variability within IQVIA information.

Reference Files

To standardize data received from a wide variety of sources and allow for alignment of the data prior to projection or aggregation, IQVIA develops and maintains reference files for various types of information, including medicines, diagnoses, treatment modalities, distribution centers, health care offices, integrated health networks, insurance plans and data classification schemes. IQVIA employs a number of processes to maintain the quality of these reference files, including: (a) acquisition and integration of a significant number of reference file updates received from a variety of sources, (b) manual data validation to confirm the existence and accuracy of the reference information, (c) maintenance of linkages between IQVIA standard identifiers and industry standard identifiers, and (d) investigations of reported data discrepancies.

Data Quality Bridging

IQVIA receives data relating to tens of millions of transactions each week. To standardize data for each transaction received from a wide variety of sources (e.g., suppliers frequently use their own proprietary reference numbers) and allow for alignment of the data prior to projection or aggregation, IQVIA links key record variables to IQVIA standard reference files as applicable for the particular service. As changes occur in the marketplace (e.g., new product or a new form, pack or strength of an existing product), and these changes are reported to IQVIA, IQVIA works quickly to map these changes in data arriving from sources to IQVIA's standard reference files. IQVIA employs a number of processes to maintain the quality and results of the bridging process, including: (a) development and maintenance of algorithms for the matching / linking of supplier reference numbers with IQVIA reference files, (b) identification of new, deleted or modified supplier reference numbers for purposes of promptly linking these to IQVIA reference files, and (c) annual bridge validation for key products.

Database Management

When data has successfully passed through the processes referenced above, it is then added to the applicable IQVIA database. In connection with the movement of the information to these databases, IQVIA employs additional quality control processes, including: (a) IQVIA examines the data to ensure data file statistics match as data moves from one process to another process (e.g., number of records), and (b) all programming logic, statistical methodologies and other computer algorithms applied to the data to create these databases and the applicable reports pass through rigorous development and testing methodologies prior to implementation in the production environment.

Projection Methodologies

Most IQVIA offerings are derived from the use of statistically representative samples, not a census of activity. More than one hundred statisticians support the development of sample designs and projection methodologies to estimate activities to achieve a high degree of accuracy on a cost effective basis. IQVIA frequently employs higher coverage rates than statistically necessary for many of its offerings to properly reflect key aspects of the pharmaceutical and health care markets.

Nevertheless, sample designs, projection methodologies and coverage rates all have an impact on the degree of accuracy of IQVIA information. Information regarding confidence intervals and other measures of accuracy are available to IQVIA customers.

Imputation Methodologies & Temporary Replacement Data

On occasion, IQVIA employs data imputation methodologies that allow IQVIA for a short period of time to impute data for a supplier or facility location if data supply is interrupted or severe data quality issues are uncovered. By using imputation methodologies for missing data, analysis has shown that IQVIA offerings are more accurate and not prone to trending spikes caused by issues in the data flow process (i.e. enabling analysis of true trends based on marketplace activities).

Client Report Creation

Certain IQVIA reports involve customization based on customer supplied report parameters (e.g., market definitions and geographic reporting specifications). IQVIA employs methods to verify the customer supplied parameters and ensure these have been properly entered into IQVIA report production systems. These customized reports undergo validation procedures in an effort to ensure these parameters have been applied correctly.

Data Availability

IQVIA provides the most comprehensive set of market measures in the world. However, numerous factors can potentially impact the acquisition and/or usability of such information, including: (a) contractual restrictions from sources of data on the use, types of customers, applications and publication of information, (b) legal restrictions, (c) data origination (e.g., data entry errors; system coding issues), (d) data suppliers (e.g., variations in processing), (e) market events, and (f) natural disasters. IQVIA works hard to avoid data variability in these circumstances and find reasonable solutions to account for the impact of these issues on IQVIA information.

Appropriate Uses of IQVIA Information

Applications using IQVIA information should be designed to accommodate the unique characteristics of the information. As noted above, there are a multitude of people, sources, systems, laws, methodologies and other issues that can impact the quality and nature of this information. Users of IQVIA information should design applications that leverage strengths and minimize weaknesses of such information to avoid application errors or flawed decision-making. These design considerations include:

- Use confidence intervals**:** Confidence intervals are expressed in terms of a range of values around the sample-based estimate associated with a particular probability, or level of confidence, that the true value is contained within that range.

- Account for normal variations in trends over historic periods of time**:** Incorporate tolerance ranges into analysis to identify data points which fall outside of normal variations. Look for industry events or other known causes which might account for the unexpected deviation. Examples might include significant weather events, product manufacturing issues affecting inventory, etc.

- Use similar historic periods when using data: Apply historical trends in tandem when viewing market share for a reasonability test (e.g., holiday periods, seasonality).

- Manage expectations**:** Set expectations within your organization and with your vendors so normal variation is understood to avoid incorrect decision-making, poorly designed applications or a loss of confidence in IQVIA information.

- Vendor selection: Be sure each of your vendors working with IQVIA data understands the related healthcare markets and the underlying characteristics associated with the data.

- Anticipate greater variability for low volume or more granular estimates: Recognize that using data on low volume products or extracting data of increasing granularity (e.g. smaller groups of prescribers or smaller geographic areas) increases the variability of the data estimations.

- Market share versus volume: Use market share for more consistency than volume. While individual product volume estimations are desirable to report product sales trends, those estimations are subject to the variability noted in this document. By viewing product trends in the context of an entire market (market shares), whereby each product is estimated with a similar degree of variability, the resulting calculations may improve the overall consistency of the market measure.

Summary

IQVIA information is gathered from a wide variety of data sources using many different methods. The data are complex, non-standard, and can be inherently variable when submitted to IQVIA. We use sophisticated tools and business practices to gather, validate, standardize, project, and report such information. As such, IQVIA information represents an estimate of measured activity and should be treated accordingly. We encourage customers to apply the considerations provided above, and to use the tools and guidance materials provided from IQVIA in order to use IQVIA information effectively.

EXHIBIT 12

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re Novartis and Par Antitrust Litigation	**1:18-cv-04361-AKH**
This Document Relates To: **All Actions**	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF DR. RENA CONTI

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Statutes & Rules

I. INTRODUCTION

Plaintiffs seek to rely on expert testimony from economist Dr. Rena Conti, who opines on the purported injury to the putative end-payor ("EPP") class. Dr. Conti's methodology, however, suffers from two critical flaws, each of which provides an independent basis for exclusion. First, Dr. Conti's analysis fails to accurately identify the consumers and third-party payors ("TPPs") that paid for brand or generic Exforge prescriptions in the specific jurisdictions that are included within the putative EPP class, while accounting for those jurisdictions that are excluded from the putative EPP class. Second, Dr. Conti's analysis fails to reliably determine how much TPPs (such as insurance companies) paid for the prescriptions at issue, a necessary predicate to calculating an accurate overcharge estimate.

II. BACKGROUND

The putative EPP class is comprised of two types of indirect purchasers: (i) consumers, who are individual purchasers of brand or generic Exforge, and (ii) TPPs, which include entities such as health plans and insurers that reimbursed some or all of the prescription price on behalf of their members or insureds. Ex. A, Conti Rpt. ¶ 14.[1] The putative EPP class is limited to those consumers or TPPs who made their brand or generic Exforge purchases in one of 22 jurisdictions.[2] *Id.* As the Court may recall, while the EPPs' complaint initially sought to include 48 jurisdictions within the putative class,

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[1] Exhibits filed herewith are attached to the Declaration of Rachel G. Skaistis.

[2] These 22 jurisdictions are: the District of Columbia, Arizona, California, Florida, Hawaii, Iowa, Maine, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Utah, Vermont, West Virginia, and Wisconsin. *Id.*

that number was reduced to 22 in the Court's rulings on the motion to dismiss. *See* Opinion and Order Granting Defs. Partial Mot. to Dismiss, ECF No. 193, at 17-19. Since that time, EPPs have not contested that the jurisdictions within their putative class are limited to those 22. As such, calculating a reliable damages estimate requires accurately identifying the operative jurisdiction for purposes of each prescription during the relevant period, as well as assessing the extent to which the indirect purchasers of those prescriptions were allegedly injured—*i.e.*, whether and how much less they would have paid absent the challenged conduct.

Dr. Conti seeks to make both determinations using a dataset her consulting firm purchased from a third party, IQVIA; the dataset is called Xponent, and it attempts to capture retail sales information for about 92 percent of all prescriptions in the country. Ex. A, Conti Rpt. ¶ 91; Ex. D, Craft Rpt. ¶ 42. The Xponent data include a "STATE" field, which Dr. Conti uses to determine which jurisdiction was the operative jurisdiction for each prescription. Ex. C, Conti Dep. Tr. at 188:2-20. The data also list an amount of monthly pharmacy reimbursement by medication, which Dr. Conti uses to determine an average, monthly per-prescription price to calculate her overcharge estimate. Ex. A, Conti Rpt. ¶ 93. For purposes of her opinions, Dr. Conti was instructed by Plaintiffs' counsel that "antitrust injury occurs at the moment of purchase", *id.* ¶ 116, and interpreted the Xponent data as providing information relevant to that moment for assessing injury to both consumers and TPPs in the putative EPP class.[3] After applying

[3] *See* Ex. C, Conti Dep. Tr. at 188:2-20 ("Q: What is the operative location for assessing which reimbursements are in the putative class? . . . A: Injury occurs at the point of sale, and therefore it's the point -- it's the place where the consumer receives the dispensed prescription. Q: And to make the determination of where the consumer received the dispensed prescription, you used the state field in the Xponent data; right?

this methodology, Dr. Conti concluded that antitrust injury can be shown using common proof, that overcharges can be reliably calculated on a class-wide basis, and that overcharges to the putative EPP class are between $94 and $130 million. Ex. A, Conti Rpt. ¶ 4.

Notably, on January 3, 2022—nearly a month after her deposition and following the close of expert discovery—Dr. Conti submitted a so-called "Second Errata," in which she admitted, for the first time, that her understanding of the "STATE" field in the Xponent data had been incorrect. Ex. B, Conti Second Errata ¶¶ 5-6. Specifically, Dr. Conti explained that on December 9, 2021—three days after her deposition—she learned that the "STATE" field "reflects the *prescriber's* location the vast majority of times," not the moment of purchase. *Id.* ¶ 5 (emphasis added). Notwithstanding this fundamental misunderstanding of the data, Dr. Conti went on to state that her "conclusions and opinions remain the same." *Id.* ¶¶ 5-6.

III. ARGUMENT

Dr. Conti's analyses rely on a flawed understanding of the Xponent data and result in an unreliable definition of the putative EPP class and overcharge estimate. Her opinions should therefore be excluded. Fed. R. Evid. 702(c) (expert testimony is only admissible if "the testimony is the product of reliable principles and methods"); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002) (expert testimony must be reliable at every step: "any step that renders the analysis unreliable . . . renders the expert's testimony inadmissible").

A: Yes, which reflects the -- for retail pharmacies, it reflects the location of the pharmacy, as I understand it.").

A. Dr. Conti's Methodology For Identifying Members of the Putative Class is Unreliable

In her expert report, and throughout her deposition, Dr. Conti asserted, without reason or explanation, that antitrust injury occurs at the "point of sale," which she assumes is the location of the pharmacy (for retail purchases) or the consumer's residence (for mail order purchases). *See, e.g.*, Ex. A, Conti Rpt. ¶ 116; Ex. C, Conti Dep. Tr. at 188:11-20.[4] She further testified that she relied upon the "STATE" field in the Xponent data to identify this geographical point of sale for purposes of her opinions. Ex. C, Conti Dep. Tr. at 192:16-23. Setting aside whether the pharmacy location or consumer's home address provide the correct metric for determining point of sale (particularly for the purpose of assessing antitrust injury for a TPP who may be hundreds or thousands of miles away from the pharmacy and consumer), the IQVIA data on which Dr. Conti relies does not provide that information. Instead, as Dr. Conti now admits, the "STATE" field in the dataset on which she relied reports on the location of the *prescribing physician*. *See* Ex. B, Conti Second Errata ¶ 5. This error calls into question all of Dr. Conti's opinions because it undermines her application of the IQVIA data.

First, there is no logical basis for suggesting that the point in time at which a consumer or TPP is allegedly injured occurs when a doctor writes a prescription for branded or generic Exforge. Neither money nor medication changes hands at that moment. Moreover, many prescriptions that are written are never filled.

[4] *See also* Ex. C, Conti Dep. Tr. at 201:13-19 ("A: Okay. Just common sense for a second, please. If I'm a consumer, I walk into a pharmacy and I am given a prescription drug from the pharmacist, that is the point of sale. It is exactly that definition of the point of sale that I am applying in assessing injury and damages in this calculation.").

Second, using the prescribing physician's location for determining class membership would be improper in instances, for example, where a consumer visited a physician in a jurisdiction other than where he or she filled a prescription, or where a TPP paid a pharmacy for a prescription in a jurisdiction other than where the medication was prescribed. For instance, Dr. Conti's approach would count as an EPP class member a consumer who visited a physician in the District of Columbia (included in the putative class definition) but filled that prescription in Maryland or Virginia (both excluded from the putative class definition). It would also count as an EPP class member an insurer based in Washington (excluded from the putative class definition) who paid for all or part of a prescription that was written in New York (included in the putative class definition), even if the insurer's payment for that prescription was made to a pharmacy in New Jersey or Connecticut (both excluded from the putative class definition).

Thus, the data Dr. Conti relies upon is insufficient to support her analysis. *See Amorgianos*, 303 F.3d at 266 ("[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony"); *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (expert opinion should be excluded when "there is simply too great an analytical gap between the data and the opinion proffered" (internal quotation marks omitted)).

Dr. Conti now attempts to rehabilitate her testimony—after her deposition and the conclusion of expert discovery—by stating that her error has no impact on the conclusions and opinions set forth in her report. Ex. B, Conti Second Errata ¶ 6. This untimely opinion lacks foundation and should also be excluded. Indeed, Dr. Conti's

revised opinion is based solely on conclusory statements that "people seek medical care within a short distance of their residence," and "prescriber state, pharmacy state, and the patient state are highly concordant." *Id.* ¶ 6. Dr. Conti—who does not claim any expertise in such matters—has not put forward any methodology, much less a reliable one, to make those determinations. They should be excluded as a result. *Pacific Life Ins. Co. v. Bank of New York Mellon*, 2021 WL 5299193, at *3 (S.D.N.Y. Nov. 15, 2021) ("Rule 702 requires that expert testimony rest on knowledge, a term that connotes more than subjective belief or unsupported speculation." (internal quotation marks omitted)).

B. Dr. Conti's Methodology For Calculating Overcharges to the Putative Class Is Unreliable

Dr. Conti's opinions should also be excluded because her methodology cannot reliably capture amounts paid for Exforge and its generic equivalents by the TPP members of the putative class. The Xponent data Dr. Conti uses to calculate overcharges attempt to capture the amounts paid to pharmacies for Exforge prescriptions.[5] Dr. Conti acknowledges, however, that many TPPs use pharmacy benefit managers ("PBMs")—who were intentionally excluded from the definition of the putative EPP class[6]—to execute their pharmaceutical purchasing, and so they reimburse the PBMs, not the pharmacies, for their members' prescriptions. *See* Ex. A, Conti Rpt. ¶¶ 171-173. [redacted]

[redacted]

[redacted]

[5] *See, e.g.*, Ex. C, Conti Dep. Tr. at 175:5-10 ("Q: You mentioned that the Xponent data that you used for your analysis is -- reflects the payment to the pharmacy for the pharmaceutical product; right? A: Correct. It is the point of sale purchase price.").

[6] End-Payor Plaintiffs' Consolidated Amended Complaint, ECF No. 25, ¶ 174(i).

[redacted] *See, e.g.,* Ex. F, UFCW LOCAL 1500-EXFG-000536–66 at -43.

Dr. Conti conceded at her deposition that in instances where it is a PBM that pays the pharmacies for Exforge prescriptions—rather than TPPs themselves—the "reimbursement" by the TPP to the PBM for a given prescription (which the TPP seeks to recover as alleged damages in this case) could be different than what is received by the pharmacy and ultimately reflected in the Xponent data for that sale. Ex. C, Conti Dep. Tr. at 166:22-167:3. This disparity could be, for example, a function of "spread pricing," whereby a TPP agrees to pay the PBM more for prescriptions than the PBM pays the pharmacy. Ex. A, Conti Rpt. ¶ 173. Or the disparity could be, for example, the result of the PBM failing to meet contracted rebate or pricing guarantees to the TPP that require the PBM to take a loss on a given prescription.[7] In either case, there is no basis to assume that the amount received by the pharmacy, as reflected in the Xponent data, is the proper metric to determine overcharges—that could allocate "damages" to TPPs that suffered no harm at all, or whose alleged harm is considerably overstated.

Dr. Conti has not investigated the extent to which there may be differences between the amounts TPPs in the putative class paid PBMs for Exforge and generic

[7] Ex. E, Rogers Dep. Tr. at 76:20 – 77:5 ("[Q:] We talked earlier about the possibility that there could be instances in which the rebates paid out to a client under rebate guarantees exceed the rebates received by Optum from the manufacturer on specific prescriptions right? A: That is a possibility, yes. Q: In those instances, does Optum take a net loss on that particular prescription? . . . .[A:] In the – in the aggregate, we could calculate a loss.").

Exforge prescriptions and the pharmacy reimbursements for those prescriptions included in the Xponent data on which she relies.[8] Dr. Conti also has not assessed, and has no basis to assume, whether any such payments by TPPs to PBMs were made in the same jurisdiction as the prescribers of the Exforge and generic Exforge prescriptions to which they are tied, which is the only geographical information Dr. Conti can draw from the Xponent data to determine which TPPs should be included in the putative class. *See* Ex. B, Conti Second Errata ¶ 5. This incomplete analysis is insufficient to meet the demanding reliability requirements of Rule 702. *See Weiner v. Snapple Beverage Corp.*, No. 07 CIV. 8742 DLC, 2010 WL 3119452, at *7 (S.D.N.Y. Aug. 5, 2010) (excluding expert report that provided "no details concerning the significant conceptual, implementation, or data issues that would be encountered if his [approach] were adopted"); *R.F.M.A.S., Inc. v. So*, 748 F. Supp. 2d 244, 274 (S.D.N.Y. 2010) ("The minimal data that [the experts] relied upon . . . provide ample reason to exclude their testimony on damages.")

IV. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court exclude the testimony of Dr. Rena Conti in its entirety.

[8] Ex. C, Conti Dep. Tr. at 175:11-176:5 ("Q: So in instances where there's a difference between the payment to the pharmacy and the payment from the third-party payer to the PBM for a given transaction, the Xponent data does not take into account that difference; correct? [A:] . . . . There might be these additional adjudications, but I think that they're out of my calculation, certainly.").

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Respectfully submitted,

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